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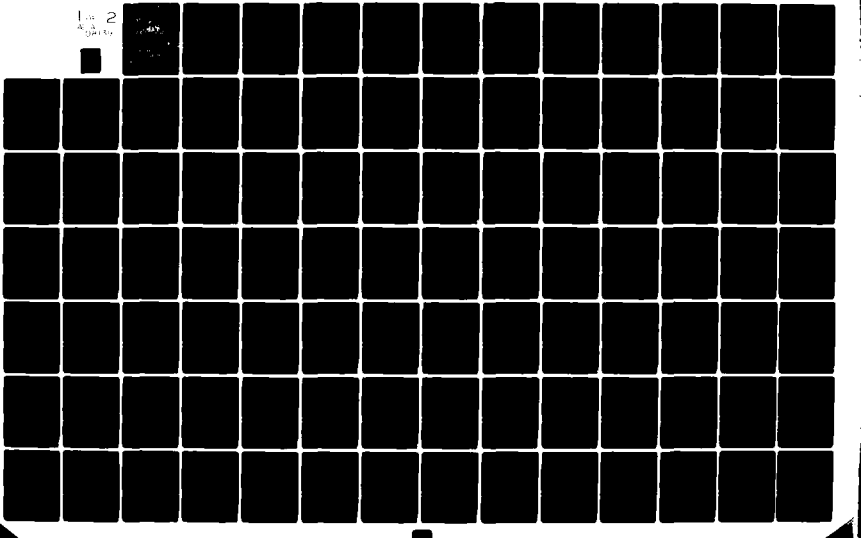

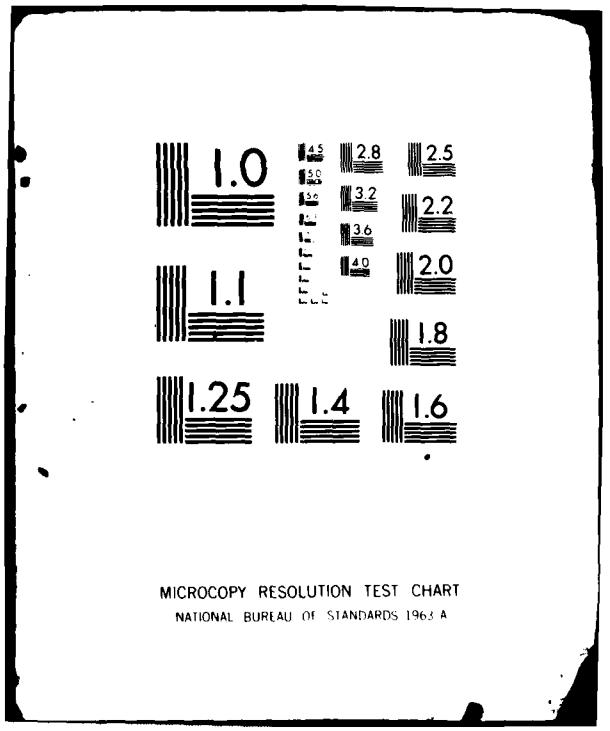
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CLINICAL · INVESTIGATION PROGRAM · REPORT

MEDICATUS·EXPERIMENTUM

DWIGHT DAVID EISENHOWER

ARMY MEDICAL CENTER
FT. GORDON, GEORGIA 30905

FY·81

CLINICAL INVESTIGATION
PROGRAM REPORT

1 October 1981

CONTROL SYMBOL: MED-300

DEPARTMENT OF CLINICAL INVESTIGATION
DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER
FORT GORDON, GEORGIA 30905

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER MED 300	2. GOVT ACCESSION NO. AD-A108 139	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle) Clinical Investigation Program Report		5. TYPE OF REPORT & PERIOD COVERED ANNUAL - FY 81 6. PERFORMING ORG. REPORT NUMBER
7. AUTHOR(s) KENT M. PLOWMAN, M.D., PhD Major, Medical Corps Chief, Department of Clinical Investigation		8. CONTRACT OR GRANT NUMBER(s)
9. PERFORMING ORGANIZATION NAME AND ADDRESS Department of Clinical Investigation Dwight David Eisenhower Army Medical Center Fort Gordon, Georgia 30905		10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS
11. CONTROLLING OFFICE NAME AND ADDRESS Commander Dwight David Eisenhower Army Medical Center Fort Gordon, Georgia 30905		12. REPORT DATE 1 October 1981 13. NUMBER OF PAGES 118
14. MONITORING AGENCY NAME & ADDRESS(if different from Controlling Office) Commander US Army Health Services Command ATTN: HSPA-I Fort Sam Houston, Texas 78234		15. SECURITY CLASS. (of this report) UNCLASSIFIED 15a. DECLASSIFICATION/DOWNGRADING SCHEDULE

16. DISTRIBUTION STATEMENT (of this Report)

APPROVED FOR PUBLIC RELEASE: DISTRIBUTION UNLIMITED

17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)

N/A

18. SUPPLEMENTARY NOTES

THE FINDINGS IN THIS REPORT ARE NOT TO BE CONSTRUED AS AN OFFICIAL DEPARTMENT OF THE ARMY POSITION UNLESS SO DESIGNATED BY OTHER AUTHORIZED DOCUMENTS.

19. KEY WORDS (Continue on reverse side if necessary and identify by block number)

Unit Summary; Detail Sheet (Study Objective, Technical Approach, Progress, Status); Publications; Presentations.

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

Subject report identifies the research activities conducted by Dwight David Eisenhower Army Medical Center investigators through protocols approved by the Institutional Review Committee for registration with the Department of Clinical Investigation during Fiscal Year 1981, and other known publications and presentations by the Dwight David Eisenhower Army Medical Center professional staff. A detail sheet of each protocol giving the objective, technical approach, and progress is presented.

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FOREWORD

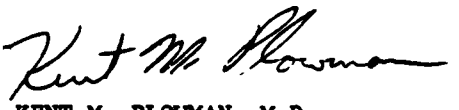
The Clinical Investigation Program at Dwight David Eisenhower Army Medical Center and the surrounding MEDDAC's has enjoyed continued, steady growth during fiscal year 1981. The growing number of protocols is only partially reflective of the burgeoning interest in scholarly pursuits. The dramatic increase in protocols from several MEDDAC's has resulted from a new emphasis on regional consultation visits by DDEAMC Clinical Investigation personnel. This increased availability for scholarly activity appears to have a beneficial effect on professional staff morale at these MEDDAC's.

The vigorous support of Brigadier General Frederick C. Biehusen, Commander, and of Colonel K. Eric Nelson, Chief of Professional Services has been invaluable to the progress that has been made.

The dedication and perseverance of the professional and technical staff during the past year despite numerous adjustments are worthy of a special recognition. A large measure of the credit for the smooth transition which has occurred goes to the Assistant Chief, Jack A. Horner, DAC, who has faithfully worked to provide continuity and stability throughout a very unsettled period for the staff.

Ms. Rosina Martinez, our Editorial Assistant, has been indispensable in her indefatiguable efforts to coordinate protocol development and to facilitate the preparation of this report.

The conduct of the research herein described was performed in accordance with AR 40-38, AR 40-7, AR 70-25, and HSC Reg 40-23 in their appropriately amended versions. Animal research adhered to AR 70-18, as amended.



KENT M. PLOWMAN, M.D.
MAJ, MC
Chief, Department of Clinical Investigation

UNIT SUMMARY - FISCAL YEAR 1981

A. Objective.

The Department of Clinical Investigation is responsible to the Chief, Professional Services for providing the facilities and atmosphere of inquiry necessary to support and stimulate both basic and clinical medical investigations within DDEAMC.

B. Technical Approach.

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-38, AR 40-7, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

C. Staffing.

Name	Rank	MOS	Title
Plowman, Kent M.	MAJ	61F9C	Chief
Arensman, John B.	MAJ	64A00	Veterinarian
Hannan, Charles J., Jr.	CPT	68Z00	Physiologist/Pharmacologist
Harris, Richard W.	CPT	68J00	Microbiologist
Sherman, Richard A.	CPT	68T9C	Psychobiologist
	E6	92B20	NCOIC
Jones, Frederick, Jr.	E6	91T20	Sen Animal Sp, Act'g NCOIC
Lohr, Edward M.	SP5	92D10	Chem Lab Sp
Blanco, Diana T.	SP5	01H20	Biological Science Asst
Jenkins, Nettie C.	SP5	74F20	Programmer/Analyst
Lohr, Patricia S.*	SP4	91T10	Animal Sp
Dunn, James C.L.	SP4	91T10	Animal Sp
Parker, Laura	SP4	91T10	Animal Sp
Horner, Jack A.	GS13	01301	S. Res Histologist
McPherson, James C. III, PhD	GS11	01320	Chemist
Patterson, Robert A.	GS9	00181	Psychology Technician
Prior, Robert	GS9	00644	Medical Technologist
Carithers, Diane	GS7	00404	Biological Lab Technician
Martinez, Rosina	GS6	01087	Editorial Assistant
Charles, Tressie**	GS4	00312	Clerk Steno
Gladney, Jeanne M.	GS4	00312	Clerk Steno
Holmes, Essie M.	GS5	00404	Biological Lab Technician (Temporary)
Silas, Bill E.	WG5	07706	Animal Caretaker

*ETS April 1980
** Transferred April 1980

D. Funding.

Type	Fiscal Year 80	Fiscal Year 81
Civilian personnel to include benefits	116,417.00	147,738.00
Consumable supplies	73,176.00	76,614.00
Civilian contracts to include consultants	1,600.00	200.00
TDY	5,266.00	7,793.00
Publications	944.00	1,055.00
Noninvestment equipment (Minor MEDCASE)	325.00	2,902.00
Other OMA	20,287.00	20,638.00
OMA Total	20,612.00	23,539.00
MEDCASE	50,767.00	132,403.00
Other	2,979.00	57.00
Military	85,959.00	225,762.00
Total	378,332.00	638,751.00

E. Progress.

Protocol Disposition FY 81

	Completed	Terminated	Ongoing to FY 82
FY 78	-	1	5
FY 79	3	3	9
FY 80	9	1	13
FY 81	13	2	26
	25	7	53

In addition to the above FY 81 total, five protocols are still going through TSG review.

F. Problems.

The fundamental problems remaining for clinical investigation are the same ones as previously identified: 1) a dilapidated, hazardous laboratory located one kilometer from the main hospital; 2) a shortage of adequate animal facilities; 3) obsolescent equipment; and 4) delays in filling critical personnel positions. Significant progress has occurred in some of these areas within the past year, but the basic problems persist.

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Code:

O - Ongoing
C - Completed
T - Terminated

P - Published
PR - Presented

PUBLICATIONS FY 81

DEPARTMENT OF CLINICAL INVESTIGATION

McPherson, J.C., Jr., and McPherson, J.C. III: Some Newly Recognized Effects of Fat Embolism. Ga J Sci, 39:80, Apr 1981. (C)

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McPherson, J.C. III: Influence of Estrogen-Progesterone and Estrogen-Androgen Combinations on Gonadotropin Secretion in Castrate Male Rats. Endocrine Society Abstract #287, p. 154, Jun 1981. (C)

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McPherson, J.C. III and McPherson, J.C., Jr.: Gastric Emptying in Experimental Fat Embolism in the Rat. Federation Proc, 40:762, 1981. (C)

McPherson, J.C., Jr., and McPherson, J.C. III: Decreased Appetite as a Newly Recognized Characteristic of Experimental Fat Embolism. Federation Proc, 40:762, 1981. (C)

Sherman, R.A.: Special Review. Published Treatments of Phantom Limb Pain. Am J Physical Med, 59(5):232-244, Dec 1980.

Rissing J.P., Buxton, T.B., Trincher, R., Harris, R.W., et al: Antigen Mediated Diagnosis of Acute Bacteroides fragilis (BF) Infections Using Enzyme Linked Immunosorbent Assay (ELISA): Observation with Lipopolysaccharide (LPS) from Serum. Clinical Research, 29:395A, 1981. (C)

Harris, R.W., Arensman, J.B. and Moore, W.L., Jr.:Characterization of a Subcutaneous Abscess Animal Model with a Bacteroides fragilis Inoculum. Ga J Sci, 39(2): 80, Apr 1981. (C)

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Haburchak, D.R., Michels, G., Hernandez, I., Wolfe, H.: Acute Respiratory Disease, Fort Gordon, Georgia. Military Medicine, 146:194-198, 1981.

Haburchak, D.R. and Moore, W.L.: Rickettsial Disease. Current Diagnosis, Conn and Conn, editors, pp 141-146, W.B. Saunders, Philadelphia, 1980.

Haburchak, D.R.: Sporadic Military Meningococcal Disease - A Diversity of Presentations. South Med J, 74(2):153-156, 1981

Johnson, W.M.: Fatal Disseminated Coccidioidomycosis Following an Intestinal Bypass Operation for Obesity. West J Med, 135:324-326, Oct 1981.

Johnson, W.M. and Kleyn, J.G.: Respiratory Disease in a Mushroom Worker. J Occup Med, 23(1):49-51, Jan 1981.

Kleyn, J.G., Johnson, W.M. and Wetzler, T.F.: Microbial Aerosols and Actinomycetes in Etiological Considerations of Mushroom Workers' Lungs. Applied Environ Micro, 41(6):1454-1460, Jun 1981.

Johnson, W.M.: Occupational Factors in Coccidioidomycosis. J Occup Med, 23(5): 367-374, May 1981.

ACCEPTED

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DEPARTMENT OF SURGERY

Edwards, F.H. and Davies, R.S.: Late Post Traumatic Obstructive Jaundice Secondary to a Biliary Tract Foreign Body. J Trauma, 1981.

DEPARTMENT OF PATHOLOGY

Riggsbee, J.H. and Lamke, C.L.: An Evaluation of the Double-Staining Procedure for the Fluorescent Treponemal Antibody-Absorption (FTA-ABS) Test. Lab Med, 12(4):232-234, Apr 1981. (C)

DEPARTMENT OF NURSING

Thompson, C., Pocklington, D. and Srsic-Stoehr, K.: Development of a Nursing Education Record Keeping System. J Cont Ed Nurs, II(5):34-43, Sep-Oct 80.

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DEPARTMENT OF PSYCHIATRY & NEUROLOGY

Bissell, W.G. and Bank, R.L.: Tricyclic Overdose. JAMA, 245:1731-1732, 1981.

Giordano, F.L. and Lemieux, R.E.: Heterosexual Panic: A Case Report. Mil Med, 146(9):650-651, Sep 1981.

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Bissell, W.G. and Giordano, F.L.: The Development of a Psychosomatic Medicine Fellowship in the US Army. Accepted by Mil Med.

Georgoulakis, J., Bank, R.L. and Jenkins, J.: Counseling Intervention in Basic Combat Training. Accepted by Mil Med.

DEPARTMENT OF FAMILY PRACTICE

Cross, G.M.: 'Second Look' Clinics. Med Bull, 37(9):28, Oct 1980.

Cross, G.M.: A Practical Appointment System for the One-Physician Clinic. Med Bull, 37(11):24-25, Nov 1980.

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Martin, J.P.: Serum Urate: The Seeress of Toxemia, Proceedings of the Annual Fellows Symposium. The Faculty Development Fellowship Program in Family Medicine, The Department of Family Medicine and Office of Medical Studies. Univ of North Carolina at Chapel Hill, Vol 2, Jun 1981.

ACCEPTED

Armstrong, R.D.: Stress in the Military Family. Accepted by Fam Prac J.

DENTAL ACTIVITY

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Hines, D. and Friedler, W.: Eosinophilic Fasciitis: An Underdiagnosed Syndrome. South Med, 74(5), May 1981.

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Griffin, E.R. III: Decubitus Ulcers: Prevention and Management. Accepted by Mil Med.

PRESENTATIONS

DEPARTMENT OF CLINICAL INVESTIGATION

McPherson, J.C. Jr. and McPherson, J.C. III: The Cholecystorinin-Secretion Like Effects of Some Non-Ionic Surface Active Agents. 63rd Annual Meeting, The Endocrine Society, Cincinnati, OH, Jun 1981.

McPherson, J.C. III and McPherson, J.C. Jr.: Gastric Emptying in Experimental Fat Embolism in the Rat. Annual Meeting, FASEB, Atlanta, GA, 1981.

McPherson, J.C. Jr. and McPherson, J.C. III: Decreased Appetite as a Newly Recognized Characteristic of Experimental Fat Embolism. Annual Meeting, FASEB, Atlanta, GA, 1981.

McPherson, J.C. Jr. and McPherson, J.C. III: Some Newly Recognized Effects of Fat Embolism. 58th Annual Meeting, Georgia Academy of Science, Atlanta, GA, Apr 1981.

McPherson, J.C. Jr. and McPherson, J.C. III: The Effects of Intravenous Pluronics F-68, F-88, and F-108 in the Rat. American Chemical Society Meeting, Dayton, OH, May 1981.

McPherson, J.C. III: Induction of Gonadotropin Surge in Estradiol Primed Castrate Male and Female Rats by Progesterone: A Sex Difference in Sensitivity to Estradiol. 58th Annual Meeting, Georgia Academy of Science, Atlanta, GA, Apr 1981.

McPherson, J.C. III: Influence of Estrogen-Progesterone and Estrogen-Androgen Combinations on Gonadotropin Secretion in Castrate Male Rats. 63rd Annual Meeting, The Endocrine Society, Cincinnati, OH, Jun 1981.

Harris, R.W., Arensman, J.B. and Moore, W.L.: Characterization of a Subcutaneous Abscess Animal Model with a Bacteroides fragilis Inoculum. 58th Annual Meeting, Georgia Academy of Science, Atlanta, GA, Apr 1981.

Blanco, D.T., Arensman, J.B. and McPherson, J.C. III: Evaluation of a Rat Model for the Clinical Fat Embolism Syndrome. 58th Annual Meeting, Georgia Academy of Science, Atlanta, GA, Apr 1981.

Hannan, C.J.: Gerbil Stroke Model: Glucose Effect. Southeast Pharmacologic Society Meeting, Augusta, GA, Nov 1980.

MEDICAL EDUCATION BRANCH

Rupple, D.L.: Vaginal Hysterectomy: A Graphic Presentation - A Series of 12 Illustrations of a Surgical Procedure. Annual Convention, Association of Medical Illustrators, Toronto, Canada, Aug 1981.

PRESENTATIONS

DEPARTMENT OF SURGERY

Jones, G.P.: Highly Selective Vagotomy, Clinical Follow Up. Gary Wratten Surgical Symposium, San Antonio, TX, May 1981.

Dales, R.L.: Pancreatic Pseudocysts, Principles of Management (DDEAMC Experience). Gary Wratten Surgical Symposium, San Antonio, TX, May 1981.

Barja, R.H.: Metastatic Septic Arthritis. Virginia Orthopedic Society, Williamsburg, VA, May 1980.

Barja, R.H.: Metastatic Septic Arthritis. Society of Military Orthopedic Surgeons, San Antonio, TX, Nov 1980.

Barja, R.H.: Pathology of the Hand Quiz, Scientific Exhibit. Annual Convention, American Academy of Orthopedic Surgeons, Las Vegas, NV, Feb 1981.

Ingeman, P.L.: Role of Therapeutic Recreation in the AMEDD. Occupational Therapy Chief Clinical Management Conference, Ft Sam Houston, TX, Jan 1981.

DEPARTMENT OF PSYCHIATRY & NEUROLOGY

Armitage, D.T.: Physical Activity and Stress Reductions. Medical College of Georgia CME Program, Augusta, GA, Apr 1981.

Armitage, D.T.: Ethical Implications of Holistic Health. DOD Region VII Chaplains Seminar, DDEAMC, Ft Gordon, GA, Jul 1981.

Armitage, D.T.: Forensic Psychiatry Update. DOD Region VII Psychiatry Conference, DDEAMC, Ft Gordon, GA, Dec 1980.

Armitage, D.T.: Organizational Development: Implications for Psychiatric Service. Department of Psychiatry, USA MEDDAC Panama, Mar 1981.

Bissell, W.G.: Placebos and the Placebo Effect. Martin Army Hospital Professional Staff Conference, Ft Benning, GA, May 1981.

Manning, R.A.: Development of Internal Controls - Infancy to Adulthood. Fort Gordon Child Care Center, Ft Gordon, GA, Jul 1981.

Rath, F.H. Jr.: One Model for Operation Planning for Psychiatric Casualties. Behavioral Sciences in the Army of the 80's Conference, El Paso, TX, Sep 1981.

Giordano, F.L.: Obesity: Problems and Prospects in the Army. Army AMEDD Behavioral Science Conference, El Paso, TX, Sep 1981.

PRESENTATIONS

DEPARTMENT OF OBSTETRICS & GYNECOLOGY

Broadnax, G.B.: Group B Beta Strep in Obstetrics Management of Pelvic Abscess. Armed Forces District-American College of Obstetricians & Gynecologists, Orlando, FL, Oct 1980.

Broadnax, G.B.: Toxic Shock Syndrome Sexually Transmitted Diseases. Armed Forces Annual Physicians Assistant Postgraduate Course, Fayetteville, NC, Apr 1981.

Broadnax, G.B.: Vaginal Hysterectomy Technique. Medical College of Georgia, Augusta, GA, Apr 1981.

Boyson, W.A.: Extraperitoneal Cesarean Section, Alternative to Antibiotics. American Association of Gynecologic Laparoscopists, Boston, MA, Jun 1981.

DEPARTMENT OF NURSING

Devin, K.: Research Opportunities and Support Persons - Open Forum. 5th Annual Nursing Research Conference, Medical College of Georgia, Augusta, GA, May 1981.

Schoch, R.: Families in the 80's. CSRA Counseling and Family Service Center, Augusta, GA, Mar 1981.

Shapiro, A.: Depression and Somatoform Disorders. Psychiatric Nursing Workshop, Medical College of Georgia, Augusta, GA, Nov 1980.

Cross, P.: Widow's Bereavement Outcomes as Influenced by Time Physically Close to Husbands Before Sudden Death. Georgia Nurses Association Annual Convention, Jekyl Island, SC, Oct 1980.

Hunn, J.: The Autonomic Nervous System. Gulf States Association of Nurse Anesthetists, Houston, TX, Oct 1980.

DEPARTMENT OF FAMILY PRACTICE

Richards, J.W.: "DOC" Radio Presentation on "Health Line," WNYC, New York, Jan 1981.

Richards, J.W.: "Family Practice" Radio presentation on "Up with Children," CBS, New York, Feb 1981.

Richards, J.W.: "DOC," Georgia Residents Association, Nov 1980; South Carolina Governors Conference, Dec 1980; Duke Faculty Development Conference, Jan 1981; Uniformed Services University of Health Sciences, Jan 1981; University of California at Los Angeles, Feb 1981; University of Maryland, Mar 1981.

Richards, J.W.: Health Education. East Virginia School of Medicine, Norfolk, VA, Jul 1981.

PRESENTATIONS

PHARMACY SERVICE

Shannon, S. Jr.: Strategic Alternatives for Managing the Challenges of the 1980's. Consultant Pharmacist Seminar, Florida A&M School of Pharmacy, Tallahassee, FL, Dec 1980.

Shannon, S. Jr. and Kutlik, K.A.: Implementation of the DataStat(R) Pharmacy System. Army Pharmaceutical Services Management Course. AHS, Ft Sam Houston, TX, Jun 1981.

SOCIAL WORK SERVICE

Platte, R.J.: Psychosocial Assessment Techniques on Working with the Patient and His Family. CSRA Families in the 80's Conference, Augusta, GA, Mar 1981.

Platte, R.J.: Psychology of the Sick, CSRA American Red Cross Volunteers, Ft Gordon, GA, Jun 1981.

Hatcher, R.W.: Use of the Life Space Diagram in Family Assessment. CSRA Family Counseling Workshop, Augusta, GA, May 1981.

Hatcher, R.W.: Military Social Work. Georgia Hospital Association of Social Workers, Augusta, GA, May 1981.

Hatcher, R.W.: Effective Counseling of the Angry Couple. University Hospital, Augusta, GA, Sep 1981.

Mann, E.R.: Treating Child Abuse in the Military. Georgia Southern University, Statesboro, GA, Mar 1981.

Mann, E.R.: Family Advocacy in the Military. Medical College of Georgia, Augusta, GA, May 1981.

Mann, E.R.: Family Violence "Spouse Abuse". Presented in a series of four panels to Ft Gordon military and civilian supervisors, Ft Gordon, GA, Sep 1981.

Benson, P.S.: Family Therapy When One Member is a Psychiatric Patient. NASW & Hospital Social Workers Association, Augusta, GA, Mar 1981.

Benson, P.S.: Family Therapy. Family Practice Residents and Faculty, Self Memorial Hospital, Greenwood, SC, Jul 1981.

Hagen, D.M.: Geneogram Presentation. Society of Hospital Social Workers, Paine College, Augusta, GA Oct 1980; Augusta Dialysis Center Social Workers, Augusta, GA, May 1981; New Social Work students, Veterans Administration Hospital, Augusta, GA, Sep 1981.

Detail Summary Sheet

Date 1 Oct 81	Prot No.: 78-5	Status: Ongoing

Title: A Vascular Occlusion Stroke Model: I. A Technique for Evaluating Therapeutic Approach and Predisposing Factors.

Start Date: Feb 78		Est Comp Date:
Principal Investigator: Charles J. Hannan, Jr., PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation, Neurology		Associate Investigators: Martin Chipman, M.D., COL, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $12,000.00	Periodic Jun 81 Review Results Continue

Study Objective: To evaluate predisposing factors and experimental therapies in the gerbil model of cerebral ischemic stroke.

Technical Approach: See Progress.

Progress: A previously described modification of the gerbil stroke model (Neurosci Abstr 6:826, 1980) developed in this laboratory allows the production of regional ischemia leading to infarction and death in about 80% of prepared gerbils within 3 days. A further 10% of animals survive with histological evidence of infarction. The procedure involves the total occlusion of the left common carotid artery, restriction of the right common carotid artery (to about 1.4mm with a tantalum ligating clip), and the i.p. injection of 2.5 gm/kg glucose in ketamine anesthetized gerbils. To evaluate the sensitivity of the model to therapeutic measures, the effect of pentobarbital on edema formation 6 hours post occlusion was measured. Edema was shown to be demonstrable by 6 hours in a group of 13 gerbils not given pentobarbital. Brains were removed, divided into quadrants, and a wet weight followed by a dry weight was obtained. The calculated percent water was significantly greater in the left hemisphere, both anterior and posterior quadrant, when compared to the right hemisphere by students t-test. When pentobarbital was used as the anesthetic (50 mg/kg) rather than ketamine, there was no difference in percent water between left and right hemispheres:

	MEAN % WATER	
QUADRANT	LEFT HEMI	RIGHT HEMI
NO TREATMENT:		
Anterior	82.2±0.90*	81.7±0.64
Posterior	80.9±1.06**	79.8±0.66
PENTOBARBITAL:		
Anterior	81.6±0.64	81.6±0.61
Posterior	80.6±0.96	80.3±0.73

*:p>.05; **:p>.01

The regional ischemia produced by this model is considered a more appropriate model for evaluation of experimental therapies than total global ischemia, and the high incidence of infarction is an advantage over the simple single common carotid occlusion model most widely used.

Detail Summary Sheet

Date 2 Oct 81	Prot No.: 78-12	Status: Ongoing

Title: Stroke Model: III. The Effect of Dexamethasone Therapy.

Start Date: FY 82	Est Comp Date:
Principal Investigator: Charles J. Hannan, Jr., PhD, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Asscciate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate dexamethasone with DMSO vehicle as an experimental therapy in the gerbil stroke model.

Technical Approach: See Protocol 78-5.

Progress: Due to advancing medical research knowledge, the appropriateness of evaluating dexamethasone therapy in the gerbil stroke model was changed to a lower priority. The dexamethasone study is planned to be implemented this year.

Detail Summary Sheet

Date 2 Oct 81 | Prot No.: 78-36 | Status: Ongoing

Title: Stroke Model: IV. The Response of Brain Superoxide Dismutase to Ischemia.

Start Date: Jan 79	Est Comp Date:
Principal Investigator: Charles J. Hannan, Jr., PhD, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Asscciate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $500.00	Periodic Revie · Results

Study Objective: To measure activity of brain superoxide dismutase in gerbil brain made ischemic for various periods of time.

Technical Approach: See Protocol 78-5.

Progress: Preliminary results look encouraging. The time commitment to this tedious project has made progress slower than anticipated.

Detail Summary Sheet

Date 8 Oct 81 Prot No.: 79-7 Status: Ongoing

Title: Control of Gonadotropin Secretion in the Male Rat.

Start Date: May 79	Est Comp Date:
Principal Investigator: James C. McPherson III, PhD, DAC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the role of estrogens, progestins and androgens either alone or in combination in the regulation of gonadotropin secretion.

Technical Approach: Immature male rats are castrated with replacement steroid therapy beginning immediately and continuing for five days. At the end of the treatment period, the animals are sacrificed, blood drawn and secondary sex organs removed and weighed as a measure of biological activity of the steroids. Blood is analyzed for serum gonadotropins by radioimmunoassay.

Progress: Previously the effects of steroids administered individually were completed. In FY 81 experiments were conducted to begin evaluating the effect of steroid combinations on gonadotropin secretion. These studies are to be continued and expanded to assess the effect of the steroids on the pituitary and/or the hypothalamus, or higher brain centers, the release of releasing factors and the role of catecholamines in this regulation.

Detail Summary Sheet

Date 8 Oct 81	Prot No.: 79-19	Status: Ongoing

Title: Gastrointestinal Hormones in Non-Ionic Surface Active Agent Induced Delay of Gastric Emptying.

Start Date: Jan 80	Est Comp Date:
Principal Investigator: James C. McPherson III, PhD, DAC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators: James C. McPherson, Jr., M.D., Medical College of Georgia
Key Words: Gastric Emptying	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the effect of non-ionic surface active agents on gastric emptying, voluntary food consumption, body weight and blood chemistries.

Technical Approach: Groups of fasted rats were given non-ionic surface active agents followed thirty minutes later by a commercial rat tube feeding diet. Animals were sacrificed at various times after feeding and gastric emptying compared to control groups. In another series of experiments, rats were injected daily for four days with non-ionic surface active agents. Voluntary food consumption before and during treatment was measured. Twenty-four hours following the last injection, the animals were sacrificed and blood drawn for blood chemistries.

Progress: A number of non-ionic surface active agents have been tested, others are yet to be tested. Their effectiveness in preventing fat embolism syndrome is being assessed under Protocol 79-22. A number of these agents show significant delayed gastric emptying, decreased voluntary food consumption and altered blood chemistries.

Detail Summary Sheet

Date 25 Sep 81	Prot No.: 79-20	Status: Completed

Title: Examination of Multi-Microbial Abscesses in Animal Models: I. Development of Abscess Implantation Methodology.

Start Date: Apr 79	Est Comp Date: May 81
Principal Investigator: Richard W. Harris, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation, Medicine	Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC William L. Moore, Jr., M.D., COL, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the most effective methods for examination of bacterial abscesses in an animal model involving continuous sampling.

Technical Approach: Gelatin capsules with Bacteroides fragilis and either sterile fecal material or soft agar were implanted in rabbits.

Progress: An abscess implantation model has been developed with sterile fecal material with Bacteroides fragilis.

Detail Summary Sheet

Date 14 Oct 81	Prot No.: 79-21	Status: Ongoing

Title: The Experimental Fat Embolism Syndrome: An Electron Microscopic Study of Lung in Three Models

Start Date: Jun 80	Est Comp Date:
Principal Investigator: Jack A. Horner, B.S., DAC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators: James C. McPherson III, PhD, DAC James C. McPherson, Jr., M.D., Medical College of Georgia
Key Words: Fat Embolism Electron Microscopy	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $1,200	Periodic Review Results

Study Objective: Experimental fat embolism syndrome is usually induced by one of five techniques: 1) fracture of the femur of an animal, 2) injection of extracted or homogenized adipose tissue from a same species donor, 3) injections of olive oil or purified triolein, 4) injection of oleic acid, or 5) injection of mineral oil (all injections given intravenously). In this study the similarity and differences, if any, in these last three techniques (olive oil, oleic acid, and mineral oil) will be investigated.

Technical Approach: Fat embolism is a major (although frequently undiagnosed unless severe) complication in patients with fractures of the long bones and/or severe trauma. The etiological mechanism of this syndrome is still unsettled. The two mechanisms most widely accepted are: 1) fat from the bone marrow of fractured bones or traumatized adipose tissue enter into small broken veins and travel to the lung where blockage of the capillaries and arterioles occur, and 2) after trauma, the circulating lipoproteins in blood coalesce to form globules of fat large enough to block the capillaries of the lung. In addition, once the fat has blocked a capillary or arteriole, the pathogenic events which follow are unclear. The major effect may be a simple blockage, but some investigators believe the most harmful effects result from the release of free fatty acids from the "trapped" fat globules in the lung. This study will attempt to establish the differences which could be important in the clinical syndrome by examining a mineral oil model (pure blockage with no possible release of free fatty acid from the globules), oleic acid (effect of free fatty acid only), and olive oil (fat capable of hydrolysis to yield free fatty acids). This study may add to our basic understanding of the events in the pathogenesis of the clinical fat embolism syndrome and suggest the basis of new methods of treatment.

Progress: After learning of the non-availability of FC-80 for use in intratracheal perfusion as originally proposed, a separate study was undertaken to evaluate several alternative preparative methods for pulmonary EM fixation. Vascular perfusion was obviously ruled out due to the possible disruption and alteration to the induced emboli. It was determined that inhalation fixation of osmium tetroxide vapors followed by low pressure perfusion of the airways with phosphate buffered osmium and cacodylate buffered glutaraldehyde was the best technique. An apparatus was assembled to administer these agents with careful control of pressure to minimize fixation artifact. This technique is currently employed in the continuation of this project. We have successfully

79-21 - Continued

isolated globules of olive oil and oleic acid at the TEM ultrastructual level, but are unable to isolate mineral oil globules due to their saturated nature, hence, they remain unfixed by the fixatives and are extracted by the propylene oxide used as a dehydrating agent. We plan to substitute hexadecene-1 for the mineral oil in order to get a "fixable" agent for further study of non-hydrolyzable blocking agents. One additional hindrance to the study was the problem associated with sampling for electron microscopy. The emboli were difficult to locate and required examination of a large number of thin sections for each experiment. This was overcome by employing the Humphrey/Spurlock ethanol cryofracture technique to examine each sample in the scanning electron microscope (SEM). This technique is very fast and easy. The complimentary face of each fractured sample was processed for TEM. Those SEM samples indicating the presence of emboli were then examined at the ultrastructural level in the TEM.

Detail Summary Sheet

Date 8 Oct 81	Prot No.: 79-22	Status: Completed

Title: The Bolus Technique for Production of Experimental Fat Embolism Syndrome Compared with a More Physiological Technique

Start Date: Jul 80	Est Comp Date: Sep 81
Principal Investigator: James C. McPherson III, PhD, DAC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the rapid injection of fat IV with a slow constant rate IV infusion of fat by evaluating the $LD_{50's}$ of the techniques in order to develop a more physiological animal model for the study of fat embolism syndrome.

Technical Approach: One group of rats were injected using the Bolus technique to determine the LD_{50} for fat. Additional groups were infused IV at various rates to determine the $LD_{50's}$ for fat. The $LD_{50's}$ were compared statistically.

Progress: Because of the promising results obtained from this study, a new and more expanded protocol was written and approved at the Sep 81 IRC meeting. The protocol was written in such a way as to allow surgery residents to participate in a meaningful manner in the study. A number of non-ionic surface active agents are to be tested for toxicity and effectiveness in preventing fat embolism syndrome.

Detail Summary Sheet

Date 25 Sep 81	Prot No.: 79-23	Status: Ongoing

Title: Examination of Multi-Microbial Abscesses in Animal Models: II. Morphological and Bacteriological Comparison.

Start Date:	Est Comp Date:
Principal Investigator: Richard W. Harris, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators: Jack A. Horner, B.S., DAC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Revie Results

Study Objective: To examine bacteriological and physiological parameters of an animal abscess model involving continuous sampling.

Technical Approach: To examine the morphological definition of abscesses by scanning electron microscopy during the development of the abscess.

Progress: This protocol will be implemented upon transfer of the Electron Microscopy Lab to the main hospital. Presently, vibration in the laboratory prevents adequate magnification of samples.

Detail Summary Sheet

Date 9 Oct 81	Prot No.: 79-31	Status: Terminated

Title: Hematologic and Biochemical Effects of Xylazine on Dogs.

Start Date:		Est Comp Date: Sep 81
Principal Investigator: J. Bruce Arensman, DVM, MAJ, VC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators: James C. McPherson III, PhD, DAC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the effects of the tranquilizer, xylazine, on hematologic, biochemical, and insulin levels in dogs and compare to known response in ruminants.

Technical Approach: After collection of blood samples at timed intervals, before and after the administration of xylazine, CBC's, SMAC-16, and insulin assays will be performed.

Progress: No work was done on this protocol during FY 81. Recent literature indicates that this information is available in enough other species, with consistent results, to justify extrapolation to the dog. Therefore, no pressing need exists for this data. Recommend termination.

Detail Summary Sheet

Date 2 Oct 81 Prot No.: 79-36 Status: Ongoing

Title: Chronic Medications and HDL-Cholesterol Screen.

Start Date: Aug 80		Est Comp Date:
Principal Investigator: Charles J. Hannan, Jr., PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation, Family Practice, Medicine, Neurology		Associate Investigators: Paul E. Martin, M.D., CPT, MC; William L. Moore, Jr., M.D., COL, MC; Edward Mendoza, M.D., LTC, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Jan 81 Results Continue

Study Objective: To monitor the effect of chronic medications on plasma high density lipoprotein cholesterol (HDL-Chol.).

Technical Approach: Plasma level of HDL-Chol. is determined in volunteers before beginning a chronic (greater than 3 week) program of a drug followed by a post drug HDL-Chol. level.

Progress: Participants in this study are continuing to accumulate patient data. The strict inclusion requirements have made this study more slowly productive than anticipated; however, an additional year may reveal some meaningful results.

Detail Summary Sheet

Date 28 Sep 81 Prot No.: 80-13 Status: Ongoing

Title: Natural Occurring Immunoglobulins in Human Serum to Bacteroides fragilis.

Start Date: Mar 80	Est Comp Date: Feb 82
Principal Investigator: Richard W. Harris, CPT, MSC	Facility: DDEAMC and VA Medical Center
Dept/Svc: Clinical Investigation	Associate Investigators: T.B. Buxton, ASCP, VAMC J.P. Rissing, M.D., VAMC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the IgM and IgG serum levels in a population of normal healthy human subjects using enzyme linked immunosorbent assay.

Technical Approach: Serum from 200 blood donors will be collected and double antibody sandwich immunoassay technique using lipopolysacchride of Bacteroides fragilis as the solid phase will be performed using antisera to human IgG and IgM.

Progress: Samples will be collected upon development of an immunoassay test for IgM. This is presently underway at the VA Medical Center.

Detail Summary Sheet

Date 9 Oct 81 | Prot No.: 80-18 | Status: Ongoing

Title: Conduit from Thoracic Duct to Esophagus: Application of New Surgical Procedure.

Start Date: Mar 80	Est Comp Date:
Principal Investigator: J. Bruce Arensman, DVM, MAJ, VC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators: A.L. Humphries, M.D., Medical College of Georgia
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To prove the efficacy of the proposed surgical procedure and to make a practical application of it. The flow of lymph into the gastrointestinal tract will result in destruction of lymphocytes and reduction of serum IgG and IgA levels to create a form of immunosuppression.

Technical Approach: Using the left jugular vein and right carotid artery, an A-V fistula is formed with the carotid artery routed through the esophageal musculature in proximity to the submucosa. In a second operation, two weeks later, the carotid and brachiocephalic vein are ligated and the lumen of the carotid opened into the esophageal lumen. Lymph can then flow from the thoracic duct through the jugular, through the transplanted carotid, into the esophagus.

Progress: During this FY all work on this model has been conducted at the Medical College of Georgia and the VA Medical Center under comparable protocols at their institutions. Progress toward the final goal of thoracic lymph shunt has been made, but slowly.

Detail Summary Sheet

Date 2 Oct 81	Prot No.: 80-21	Status: Completed

Title: Cognitive Style in Acute Schizophrenics.

Start Date: Jul 80	Est Comp Date: Sep 81
Principal Investigator: Charles J. Hannan, Jr., PhD, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation, Psychiatry	Asscciate Investigators: Matthew E. Levine, M.D., LTC, MC Raymond Klein, PhD
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if normal rhythms of cognitive style (verbal versus spatial performance) are present in schizophrenic volunteers.

Technical Approach: Volunteers with a diagnosis of schizophrenia take the cognitive style test intermittently for an entire day to reveal patterns of verbal and spatial ability during an extended period.

Progress: A total of six patients (out of 10) completed the cognitive style test and the raw data has been forwarded to Dr. Klein for computer analysis. The initial impression from the results is that the patients' response rates were too low to generate analyzable results. The lack of attention of the patients is considered the cause of this low rate.

Detail Summary Sheet

Date 28 Sep 81 Prot No.: 80-29 Status: Ongoing

Title: Differentiation of Bacteria in vivo by Gas Liquid Chromatography.

Start Date: Nov 81	Est Comp Date:
Principal Investigator: Richard W. Harris, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC William L. Moore, Jr., M.D., LTC, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine patterns of metabolite production by electron capture gas chromatography in an abscess animal model.

Technical Approach: Exudate from the rabbit model will be used to compare monomicrobial abscesses. Organisms will be implanted with soft agar and exudate will be examined upon abscess formation. Serum will be drawn for determination of metabolites.

Progress: This protocol will be implemented upon completion of a TDY by CPT Harris to the Center for Disease Control to be trained in analysis of data by this system.

Detail Summary Sheet

Date 28 Sep 81	Prot No.: 80-30	Status: Ongoing

Title: Detection of B. fragilis Antigen in vivo.

Start Date: Oct 80		Est Comp Date: Mar 82
Principal Investigator: Richard W. Harris, CPT, MSC		Facility: DDEAMC and VA Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators: William L. Moore, Jr., M.D., LTC, MC J. Peter Rissing, M.D., VA Med Ctr Thomas B. Buxton, M.S. (ASCP), VAMC J. Bruce Arensman, DVM, MAJ, VC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To use the enzyme linked immunoassay (ELISA) to detect B. fragilis in serum in an animal model.

Technical Approach: Two separate determinations will be made; a) detection of antigen in a rat bacteremia model, and b) detection of antigen in a rabbit abscess model.

Progress: Detection of B. fragilis lipopolysacchride in serum of rats with a three-day old subcutaneous abscess was accomplished. Differentiation could be made from abscesses with bacteria in the family Enterobacteriaceae. Results will be published in the November issue of Journal of Clinical and Laboratory Medicine. Assessment of Lipopolysaccharide and outer membrane of Bacteroides fragilis by an antibody inhibition ELISA in physiologic fluids and infected animals.

Detail Summary Sheet

Date 1 Sep 81 | Prot No.: 81-16 | Status: Ongoing

Title: Correlations Between Amount of Information Feedback and Success of Biofeedback Treatments.

Start Date: Feb 81		Est Comp Date: Mar 83
Principal Investigator: Richard A. Sherman, PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation, Psychology Service		Associate Investigators: Ralph Bruno, PhD, CPT, MSC
Key Words: Biofeedback, Learning, Information, Bruxism, Subluxation of Patella		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether increasing the amount of information about muscle tension given to patients with muscular control problems will shorten treatment times and increase the overall effectiveness of the treatment.

Technical Approach: For patients with Bruxism, half receive muscle tension feedback from the masseter muscle, weekly in the laboratory, and wear a masseter tension monitor nightly at home. The other half does the same with the addition of receiving feedback from the night monitor when they begin tensing their jaws. For patients with subluxation of the patella, muscle tension in the vastus medialis and lateralis will be recorded. Half will receive a combined feedback proportional to their relative tension and half will receive two independent signals juxtaposed in various ways indicating both relative and absolute muscle tension.

Progress: All equipment for the bruxism portion of the study has recently arrived, but the home recorders have not yet been modified to automatically record amount of home bruxing. The first 12 trial subjects are in various stages of the laboratory treatment. A total of 120 treatment sessions have been run to date. The subluxation portion of the study is being held at a trial stage because the graphs generation system required for one portion of the study is not scheduled for order until the second quarter of 1982. Four trial subjects have been seen in 29 sessions.

Detail Summary Sheet

Date 1 Sep 81 Prot No.: 81-17 Status: Ongoing

Title: Intrasession Psychophysiologic Arousal Correlates of Psychotherapy and Behavior Treatment.

Start Date: Feb 81	Est Comp Date: Dec 82
Principal Investigator: Richard A. Sherman, PhD, CPT, MSC	Facility: DDEAMC
Dept/Svc: Clinical Investigation, Psychiatry & Neurology	Associate Investigators: John McCormack, PhD, LTC, MSC William G. Bissell, M.D., LTC, MC Ralph Bruno, PhD, CPT, MSC
Key Words: Arousal Psychotherapy	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To monitor patterns of arousal among patients undergoing group psychotherapy, individual psychotherapy, or individual behavior therapy to detect correlations between therapeutic work/intervention and arousal (as reflected by psychophysiologic parameters) during a session.

Technical Approach: Patients in the above settings will be instrumented appropriately so that various psychophysiologic parameters indicative of arousal (heart rate, respiration rate, number of GSR's, muscle tension, peripheral vasoconstriction, etc.) can be continuously monitored throughout a session. All verbal interactions will be recorded on a second by second basis on the physiologic data tape to permit correlation between arousal and therapy.

Progress: All physiologic monitoring equipment required to carry out the study was ordered and has now arrived. A remote psychophysiologic recording system was developed to permit interference limited recordings made in group therapy room to be transmitted to the control room. This system and the attendent verbal transcription techniques have been tested and perfected. Data gathering will begin as soon as an appropriate and agreeable psychotherapeutic group is started.

Detail Summary Sheet

Date 1 Sep 81	Prot No.: 81-18	Status: Ongoing

Title: Environmental Stress and Electromyographic Correlates of Chronic Posterior Trunk Muscle Pain.

Start Date: Feb 81		Est Comp Date: Dec 83
Principal Investigator: Richard A. Sherman, PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation, Psychology, Orthopedics		Associate Investigators: John McCormack, PhD, LTC, MSC Jack K. Tippens, M.D., COL, MC
Key Words: Low Back Pain Upper Back Pain Muscle Tension		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To record those muscles in the posterior trunk of patients with lower and upper back, shoulder, or neck pain related to abnormal muscle tension in order to ascertain relationships between stress, pain, and tension as well as evaluate the effectiveness of muscular relaxation training as a treatment for these problems. The relative effectiveness of these treatments for pain in the above areas with and without underlying muscle tension problems will be evaluated.

Technical Approach: Recordings of muscle tension; objective psychosomatic measures of stress, anxiety, functional locus and other factors; discomfort logs; and other measures will be made before, during and after muscle relaxation treatments of people with the problems described above. These progressive measures will be compared with identical measures made of people with: 1) musculoskeletal related pain in other areas, 2) high anxiety but no musculoskeletal pain, and 3) posterior trunk pain but no muscle tension problem. A second phase of the study will consist of continuous muscle tension recordings made throughout the day using wearable EMG recorders. These measures will be related to a continuously tape recorded log of environmental loci and stresses.

Progress: All equipment required to carry out the first phase of the study has now arrived. This phase is in progress with 26 subjects participating to date and 181 recording sessions having been completed. Insufficient data are available to reach any conclusions at this time.

Detail Summary Sheet

Date 1 Sep 81 Prot No.: 81-19 Status: Ongoing

Title: Investigations of Chronic Phantom Pain.

Start Date: Feb 81	Est Comp Date: Jan 85
Principal Investigator: Richard A. Sherman, PhD, CPT,MSC	Facility: DDEAMC; AMVAH San Antonio; VAMC Augusta
Dept/Svc: Clinical Investigation	Associate Investigators: Norman Gall, M.D., AMVAH San Antonio Andree J. Lloyd, PhD, VAMC, Augusta Jack K. Tippens, M.D., COL, MC, DDEAMC
Key Words: Phantom Pain	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To 1) develop an understanding of the underlying causes of phantom pain; 2) determine the extent of phantom pain among the amputee population; 3) develop comparative differential profiles of amputees with and without phantom pain; and 4) evaluate new treatments of phantom pain.

Technical Approach: All service connected amputees who can be located receive a mail survey requesting information about their amputation, stump pain, phantom pain, etc. All service connected veterans living near DDEAMC and all amputees treated at DDEAMC or VAMC Augusta are asked to participate in a psychometric and psychophysiologic profile. All phantom pain patients seen at any participating center receive the same profile as part of the pretreatment workup.

Progress: A trial set of surveys has been sent out to test the instrument and permit evaluation of initial trends. More than 60% were returned and analysis is in progress. The major finding to date is that over 80% of respondents report medically significant amounts of phantom pain. The expected rate of phantom pain was about five percent. With 60% responding, even if all nonrespondents were free of phantom pain, the percentage reporting sufficient phantom pain for their lives to be greatly affected is still astoundingly high. The reasons for amputees not reporting phantom pain to their physicians are being evaluated.

Seven amputees have been evaluated at DDEAMC to date (46 sessions), but results are not complete and the profile called for in the protocol cannot be produced because most of the equipment required to develop the protocol has not been ordered yet.

Detail Summary Sheet

Date 5 Oct 81	Prot No.: 81-42	Status: Ongoing

Title: Experimental Fat Embolism Syndrome: Basic Studies and Evaluation of Currently Available Therapies and New Agents.

Start Date: Oct 81	Est Comp Date:
Principal Investigator: James C. McPherson III, PhD, DAC	Facility: DDEAMC
Dept/Svc: Clinical Investigation	Associate Investigators: Jack A. Horner, DAC J. Bruce Arensman, DVM, MAJ, VC Robert Prior, DAC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Evaluation of current therapies and new therapies for treatment of fat embolism syndrome in an experimental animal model.

Technical Approach:

Progress: This study approved locally Sep 81, insufficient time to implement during FY 81.

Detail Summary Sheet

Date 31 Aug 81	Prot No.: 81-14	Status: Completed

Title: A Study of the Central Appointment System at Dwight David Eisenhower Army Medical Center.

Start Date: Jan 81	Est Comp Date: Jun 81
Principal Investigator: Dennis L. Chaffee, CPT, MSC	Facility: DDEAMC
Dept/Svc: Administrative Resident	Associate Investigators:
Key Words: Central Appointment System	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To identify problems within the current centralized outpatient scheduling system through an analysis of selected data; 2) To determine the perceptions of the professional staff and randomly selected patients concerning the Central Appointment System through administration of questionnaires; and 3) To recommend both long-range and short-range improvements to the present system through appropriate analysis of the information and data that is obtained.

Technical Approach: The information and data necessary to conduct an evaluation of the present system was obtained through four primary methods. There were: 1) Measurement of selected system workload data; 2) Individual clinic information surveys; 3) Opinion questionnaires; and 4) Key personnel interviews.

Progress: The purpose of this study has been to examine the efficiency and effectiveness of the Central Appointment System (CAS) within this facility. An analysis of the data allows several conclusions to be made. For this study, effectiveness has been defined as the amount of appointments made by CAS compared to the total number of clinic appointments. It was shown that CAS is appointing approximately 15 percent of all appointed clinic visits. Even when it is considered that only 44 percent of the clinics are subject to CAS, this amount is still low and not indicative of a fully effective system. Conversely, the efficiency of CAS, defined as the number of calls received per clerk is comparatively high. It was found that each clerk, on the average, handles 100 to 150 calls per day. Although idle time was observed, it must be remembered that CAS efficiency is directly related to the number of providers and the time of day and month. It is felt that the current system has only minimal expansion ability without severely hampering the overall system. Both the provider and patient surveys indicated a dissatisfaction with CAS. Sixty-seven percent of providers and 56 percent of the patients surveyed would opt for a totally decentralized system. These rates could be related to the fact that the current system is a mixture of both centralized and decentralized systems. Based upon the above conclusions, it is recommended that consideration be given to dissolving the present CAS.

Detail Summary Sheet

Date 9 Oct 81	Prot No.: 78-35	Status: Terminated

Title: General Dentistry Resident Surgical Instructional Experience Development and Implementation of a Program.

Start Date: Nov 78	Est Comp Date: Sep 81
Principal Investigator: William R. Schriver, LTC, DC	Facility: DDEAMC
Dept/Svc: Dental Activity, Clinical Investigation	Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To develop and implement an audiovisual and practical training program involving surgical instrumentation, suture materials, sterile technique, anesthesia and surgery for the General Dentistry Residents. 2) To provide a meaningful, highly structured course of direct surgical and anesthesia experience in Clinical Investigation Laboratories.

Technical Approach: Through the use of didactic and hands-on instruction techniques, a program of instruction is to be developed implementing the above objective.

Progress: Program was taught to seven Dental Residents during FY 81. Due to curriculum pressures and the fact that this FY is the final year for the General Dentistry Program, this program of instruction is not now being taught. Recommend termination.

Detail Summary Sheet

Date 16 Oct 81	Prot No.: 79-29	Status: Terminated

Title: Tissue Reaction in the Oral Mucosa to Surgical Silk Suture, Synthetic Polyester Fiber Suture, and Monofilament Suture.

Start Date: Jul 79	Est Comp Date: Sep 81
Principal Investigator: Elmer J. Neaverth, DC, COL	Facility: DDEAMC
Dept/Svc: Dental Activity, Clinical Investigation	Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To study the tissue reaction in oral mucosa to various suture materials.

Technical Approach: Mersiline, silk, nylon sutures were placed in the oral mucosa of four dogs.

Progress: The clinical approach has been completed on four dogs in FY 80. Due to inactivity during FY 81, study is terminated.

Detail Summary Sheet

Date 8 Oct 81	Prot No.: 80-3	Status: Ongoing

Title: Penetration of Topically Applied Carbon 14 Tagged 2% Lidocaine on Dog Oral Mucosa.

Start Date: Feb 80	Est Comp Date:
Principal Investigator:	Facility: DDEAMC
Dept/Svc: Dental Activity, Clinical Investigation	Associate Investigators: Charles J. Hannan, Jr., PhD, CPT, MSC James C. McPherson III, PhD, DAC
Key Words: Lidocaine, Adsorption	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Topically applied local anesthetics are used to relieve pain from ulcers and wounds, to anesthetize mucosa prior to injection and to inhibit a gag reflex. These agents can be administered as ointments, gels, solutions, pastes and sprays. The chemical and physical form in which these agents are administered, along with the method of administration affect their adsorption. In dentistry, it would be important to minimize the effect of pain due to injection or other dental procedures by maximizing the effectiveness of these agents. This study was undertaken to study the penetration and adsorption of Lidocaine jelly in the oral mucosa of dogs.

Technical Approach: Carbon-14 labeled Lidocaine HCl was added to a 2% Lidocaine-HCL jelly. This mixture was applied to the oral mucosa in each experimental site (one in each quadrant of the mouth) using a retaining 10mmx6mm wire template. After appropriate time intervals, the template was removed, the templated area swabbed three times with ethanol moistened gauze sponges and two 3mm punch biopsies taken. Appropriate control biopsies were taken in adjacent areas not receiving the Lidocaine agent. The tissue samples were solublized and counted in a liquid scintillation counter.

Progress: This research protocol has been inactive during FY 81, pending the acquisition of a research grade liquid scintillation counter, and the Dental Activity providing a new Dental Resident to continue the project.

Detail Summary Sheet

Date 18 Aug 81	Prot No.: 81-1	Status: Completed

Title: A Comparison of Cleaning Techniques for Diamond Burs.

Start Date: Nov 80		Est Comp Date: Jul 81
Principal Investigator: Richard L. Emert, CPT, DC		Facility: DDEAMC
Dept/Svc: Dental Activity, Clinical Investigation		Associate Investigators: David Cunningham, LTC, DC Jack A. Horner, DAC
Key Words: Burs Cleaning Diamond Burs		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the most effective method to rid the diamond bur of debris collected during dental procedures.

Technical Approach:
1. Dental procedures done on new, unused diamond burs.
2. Burs cleaned by one of four methods.
3. Burs studied and compared using Scanning Electron Microscopy.

Progress: Best cleaning methods for diamond burs is either soap scrub technique or ultrasonic cleaning technique.

Detail Summary Sheet

Date 18 Aug 81	Prot No.: 81-2	Status: Completed

Title: The Incidence of Female Soldiers' Dental Sick Call.

Start Date: Nov 80		Est Comp Date: Jul 81
Principal Investigator: Rita M. Schleyer-Foley, CPT, DC		Facility: DDEAMC
Dept/Svc: Dental Activity		Associate Investigators:
Key Words: Dentistry Emergency Women Health Needs Female vs Male Sex Military Med Female vs Male		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if more women than men, proportionate to total population at Ft Gordon, seek emergency dental care.

Technical Approach: Six-month retrospective study of Tingay Dental Clinic's log sheets for emergency care treatment by sex.

Progress: There is a significant difference between total female population on post and total female population at dental sick call. More females than males show up at sick call. Due to incomplete data collection design, however, the results should be viewed as inconclusive.

Detail Summary Sheet

Date 19 Aug 81 Prot No.: 81-3 Status: Completed

Title: A Comparison of Radicular vs Pin Retained Composite Build-ups in Endodontically Treated Teeth.

Start Date: Nov 80		Est Comp Date: Jun 81
Principal Investigator: Timothy J. Kaigler, CPT, DC		Facility: DDEAMC
Dept/Svc: Dental Activity		Associate Investigators:
Key Words: Endodontics Pins Build-up Restoration		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the resistance to stress of radicular vs pin retained composite build-ups in endodontically treated teeth.

Technical Approach:
1. Performed endodontics on extracted human teeth.
2. Constructed pin and radicular retained build-ups.
3. Compared resistance to stress using Intran testing machine.

Progress: This study found that radicular retained composite build-ups are superior to pin retained composite build-ups in resistance to applied stress.

Detail Summary Sheet

Date 19 Aug 81 Prot No.: 81-4 Status: Completed

Title: Pain Apperception in the Dental Anxiety Clinic.

Start Date: Nov 80		Est Comp Date: Jun 81
Principal Investigator: Elizabeth L. Griffin, CPT, DC		Facility: DDEAMC
Dept/Svc: Dental Activity		Associate Investigators:
Key Words: Pain Dental fear Anxiety		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if the Pain Apperception Test is useful in the Dental Anxiety Clinic and if patients' dental fears lessen after treatment in the Dental Anxiety Clinic.

Technical Approach: Pre and post treatment to 10 anxiety patients and 10 control patients using PAT by Petrovich and Spillberger self evaluation.

Progress: 1) Pain Apperception Test not useful in Dental Anxiety Clinic, and 2) All patients had a reduction in dental fears that participated in the Dental Anxiety Clinic.

Detail Summary Sheet

Date 19 Aug 81 Prot No.: 81-5 Status: Completed

Title: A Study of the Position of the Parotid Papilla Relative to the Occlusal Plane.

Start Date: Nov 80		Est Comp Date: Jul 81
Principal Investigator: Patrick F. Foley, CPT, DC		Facility: DDEAMC
Dept/Svc: Dental Activity		Associate Investigators:
Key Words: Parotid Papilla Removable Prosthodontics Occlusal Plane Complete Dentures Plane of Occlusion		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the relationship of the parotid papilla to the occlusal plane.

Technical Approach: Collection of data by direct measurement of the distance between the parotid papilla and plane of occlusion on each side of the mouth in each subject.

Progress: A fairly constant relationship between the parotid papilla and the occlusal plane was found. It was noted that the measurements for the right side differed statistically from those for the left. Clinical significance is attached to the findings with regard to complete denture fabrication and removable prosthodontics.

Detail Summary Sheet

Date 19 Aug 81	Prot No.: 81-6	Status: Completed

Title: The Effect of Local Anesthetic Temperature on Pain Perception.

Start Date: Dec 80		Est Comp Date: Jun 81
Principal Investigator: Charles R. Weber, CPT, DC		Facility: DDEAMC
Dept/Svc: Dental Activity		Associate Investigators: LTC Thomas F. Payne, DC
Key Words: Local anesthesia Pain Temperature		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the effect on pain perception of warming a local anesthetic solution to body temperature prior to injection and to compare it to injections at room temperature.

Technical Approach: Thirteen adult subjects were given two simultaneous injections of 2% xylocaine with 1:100,000 epinephrine in the maxillary anterior vestibule, one at 37°C, the other at 22°C. Subjects were asked to report their perceived pain using a questionnaire.

Progress: Results suggest that patients are unable to detect any consistent differences in pain perception between simultaneous local anesthetic injections at 37°C and 22°C.

Detail Summary Sheet

Date 19 Aug 81	Prot No.: 81-7	Status: Completed

Title: The Reliability of Using the Nasopalatine Papilla as a Guide in Positioning Denture Teeth.

Start Date: Dec 80		Est Comp Date: Jun 81
Principal Investigator: Craig H. Ricks, CPT, DC		Facility: DDEAMC
Dept/Svc: Dental Activity		Associate Investigators:
Key Words: Reliability, Nasopalatine Papilla, Guide, Midline		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if the nasopalatine papilla was a reliable guide to use when positioning anterior denture teeth.

Technical Approach: Modified Bitefork and Boley gauge was used to measure deviation of maxillary lip midline from bitefork extension which represented position of nasopalatine papilla.

Progress: The results showed that the dental midline and the facial midline showed a discrepancy of 0.5 to 4.9 mm in 50% of the cases. It was concluded that the nasopalatine papilla in most cases was an acceptable landmark.

Detail Summary Sheet

Date 14 Oct 81 Prot No.: 79-26 Status: Terminated

Title: Family Practice Resident Surgical Instructional Experience.

Start Date: Jun 79	Est Comp Date: Sep 81
Principal Investigator: Phillip W. Blair, M.D., CPT, MC	Facility: DDEAMC
Dept/Svc: Family Practice, Clinical Investigation	Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the benefits of trauma management training using animal models among Family Practice Residents.

Technical Approach: In an appropriately anesthetized animal, several emergency procedures will be performed to gain skill and proficiency in:

Cut downs	Tracheotomies	CPR
Arterial lines	Thoracotomies	
Peritoneal lavage	CVP placement	

Expectations and evaluations of the course will be compared to individual experience levels.

Progress: Approximately 20 half-day sessions were conducted during FY 81. These sessions were for development of techniques and experience by using animal models of human emergencies. Significant progress was made and all of the above techniques can be taught. The principal investigator has PCS'd. If another principal investigator is named, a new protocol will be submitted.

Detail Summary Sheet

Date 28 Sep 81	Prot No.: 79-37	Status: Ongoing

Title: Routine Use of Serum Uric Acid Levels at 36 Weeks Gestation as Screening Test for Preeclampsia as an Aid to Further Management.

Start Date: Jan 80		Est Comp Date:
Principal Investigator: Paul J. Martin, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Family Practice		Associate Investigators: CPT Ellis M. Knight, MC
Key Words: Serum Uric Acid Preeclampsia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Jan 81 Continue

Study Objective: To demonstrate that: A. Serum uric acid level is a simple specific screening test for preeclampsia at 36 weeks gestation; B. Its prognostic significance is great enough to warrant its use as a routine lab parameter in all pregnancies. To investigate effects of age and multiparity on serum urate levels.

Technical Approach: Seventy-six randomly selected pregnant women presenting for routine prenatal care at the DDEAMC Family Practice Clinic were included in this study. A serum SMA-18 screening chemistry analysis was drawn on each of these women at 36 weeks gestation. This screening profile included uric acid levels. After delivery, a chart review was done on each patient and they were categorized into one of the following areas: uncomplicated pregnancy, gestational hypertension, preeclampsia, or severe preeclampsia.

Progress: This study was undertaken to determine the predictive value of serum uric acid levels (SUA) in identifying women at high risk for Pregnancy Induced Hypertension (PIH or preeclampsia). Twnety-five women presenting during pregnancy were followed prospectively with serial serum uric acid levels on initial visit, at 36 weeks gestation, during labor, and six weeks postpartum. These patients were managed in a routine fashion with no knowledge of the SUA levels by their physician. Two of the women developed the clinical symptoms of PIH (hypertension, significant proteinuria, and/or central edema). Both women had 36 week SUA levels $\geq$ 6.0 mg%. None of the patients with SUA levels $\leq$ 5.0 mg% had any of the symptoms of PIH. Although the numbers are small in this ongoing study, it appears that a 36 week gestation SUA level $\geq$ 6.0 mg% places a woman at high risk for subsequently developing the clinical manifestations of PIH. Likewise, a SUA level $\leq$ 5.0 mg % at 36 weeks gestation places a woman in a low risk category for developing PIH. Study is continuing to increase the numbers.

Detail Summary Sheet

Date 21 Oct 81	Prot No.: 81-31	Status: Ongoing

Title: Use of C-Reactive Protein in Prediction of ARD Prognosis.

Start Date: Jun 80	Est Comp Date:
Principal Investigator: David L. Maness, M.D., CPT, MC	Facility: DDEAMC
Dept/Svc: Family Practice, Medicine, Pathology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if prospective measurement of C-reactive protein in sera of ARD patients will predict those with significant bacterial infection.

Technical Approach: 100 consecutive ARD patients will have CRP values determined on admission. This will be performed on blood drawn for VDRL and will not require additional needle sticks. In analysis of data, CRP levels at admission will be correlated with antibiotic use, length of hospital stay, peak first day temperature, bacterial pathogen isolation, chest x-ray result, clinical diagnosis and virologic diagnosis.

Progress: No reportable data available.

Detail Summary Sheet

Date 21 Oct 81	Prot No.: 81-40	Status: Ongoing

Title: The Assessment of Improved Physiologic Function With a Short Term Exercise Program in Mildly to Moderately Obese People.

Start Date: Aug 81		Est Comp Date:
Principal Investigator: Jeannette E. South, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Family Practice		Asscciate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To assess whether there is significant improvement in cardiovascular and pulmonary parameters with a short term exercise program in young people (ages 20-40) who are mildly to moderately obese (10-30% above ideal body weight).

Technical Approach: Study designed to include 60 participants in a weight loss/ exercise training regimen for a period of sixty days. The only variable that will actually be studied will be improvement in exercise tolerance.

Progress: No reportable data available.

Detail Summary Sheet

Date 3 Sep 81 Prot No.: 78-38 Status: Ongoing

Title: Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings. Part I. Human Immunologic Reactivity to Fire Ant Antigens. BB IND 1452

Start Date:		Est Comp Date:
Principal Investigator: Chester T. Stafford, MD, COL, MC		Facility: DDEAMC
Dept/Svc: Medicine/Immunology, Clinical Investigation		Associate Investigators: Robert B. Rhoades, MD, Medical College of Georgia Charles J. Hannan, Jr., PhD, CPT, MSC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results Apr 81 Continue

Study Objective: (1) To compare the skin test reactivity of fire ant venom and its components with whole body extracts (WBE) of fire ants in patients allergic to stings of the imported fire ant. (2) To compare skin test reactivity with in vitro immunologic studies (RAST and Histamine release). (3) To determine the pretreatment immunologic status of fire ant sensitive patients prior to their participation in studies comparing the relative efficacy of immunotherapy with fire ant venom (Part III Protocol) versus whole body extracts (Part II Protocol) versus placebo; pending DA approval. (Part IV on separate summary sheet).

Technical Approach: In order to meet FDA requirements for beginning human skin testing, the fire ant products must be evaluated for toxicity and uniformity of composition according to Title 10, US Code.

Progress: Further activity on Part I of this study has been postponed pending the completion of Part IV, In Vitro Testing of Allergenic Substances, BB IND 1452.

Detail Summary Sheet

Date 1 Oct 81	Prot No.: 78-38	Status: Ongoing

Title: Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings. Part IV - In vitro Testing of Allergenic Substances. BB IND 1452.

Start Date: Aug 79	Est Comp Date:
Principal Investigator: Chester T. Stafford, M.D., COL, MC	Facility: DDEAMC
Dept/Svc: Medicine/Immunology, Clinical Investigation	Asscciate Investigators: Charles J. Hannan, Jr., PhD, CPT, MSC Robert B. Rhoades, M.D., Medical College of Georgia
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $600.00	Periodic Review: Apr 81 Results Continue

Study Objective: Parts I, II and III of this protocol will be conducted under regulations for an Investigational New Drug (IND) and; therefore, production lots of allergens produced at DDEAMC must be subjected to a series of specific evaluations. Tests to be performed include evaluation of: 1) potency, 2) general safety, 3) sterility, and 4) purity as specified in Title 21, Code of Federal Regulations.

Technical Approach: N/A

Progress: Collection of fire ant venom and body parts for allergen preparation are continuing with approximately 200 microliters of whole venom collected to date. Part IV of this protocol has been written and submitted to HSC for forwarding to FDA. This Part IV outlines the details of allergen preparation so the substances will be suitable for human use.

The investigators wish to express their gratitude to SP5 Richard Garcia who has contributed his technical support up to 23 September 1981 when his untimely death occurred.

Detail Summary Sheet

Date 20 Oct 81	Prot No.: 79-34	Status: Ongoing

Title: Growth of Human Tumor Stem Cell Colonies in Soft Agar.

Start Date: Jan 80		Est Comp Date:
Principal Investigator: James F. Boyd, M.D., LTC, MC		Facility: DDEAMC
Dept/Svc: Medicine, Pathology		Associate Investigators: Cherry Gaffney, M.D., CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Jan 81 Results Continue

Study Objective: To grow human tumor stem cell colonies in soft agar for the purpose of studying growth kenetics, sensitivity to chemotherapeutic and hormonal agents, and to study estrogen receptors in the cytoplasm of malignant cells by immunofluorescent assay.

Technical Approach: Single cell suspension of the human cancer cells will be obtained from pleural, paracardial or ascitic fluid. These cells will be suspended in a 0.3 percent agar overlayer with a 0.5 percent agar underlayer providing necessary nutrients for growth. Various hormones and/or chemotherapeutic agents can be mixed with the tumor cells in the overlayer to determine toxicity to the cells by measurement of the number of colonies which grow subsequently. Additionally, a fluorescent labeled conjugate is being studied which will tag estrogen receptors. This is particularly of value in determining responsiveness of breast cancer to hormone therapy. The immunofluorescent assay is being developed to assay the percentage of colonies which are estrogen receptor positive.

Progress: See progress on protocol 81-20.

Detail Summary Sheet

Date 1 Oct 81 Prot No.: 79-35 Status: Ongoing

Title: Rapid Diagnosis of Viral Respiratory Infection.

Start Date: Feb 80	Est Comp Date:
Principal Investigator: David R. Haburchak, M.D., LTC, MC	Facility: DDEAMC
Dept/Svc: Medicine/Infectious Disease, Clinical Investigation	Associate Investigators: Richard W. Harris, CPT, MSC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine feasibility of rapid viral diagnosis in patients with ARD by methods of direct electron microscopy and enzyme-linked immunoabsorbant assay.

Technical Approach: Throat swabs from patients with ARD are inoculated into holding medium, split, cultured, processed for EM and ELISA.

Progress: 1) Direct electron microscopy has been determined not to be feasible with current methodology. An attempt will be made using differential centrifugation using a recently acquired ultracentrifuge. 2) New ELISA reading equipment has arrived. New studies will be performed this fall after arrival of specific anti-adenovirus and anti-influenza linked sera. 3) An additional arm of the study will look for adenovirus and influenza antigen using immunofluorescent technique.

Detail Summary Sheet

Date 6 Oct 81 Prot No.: 80-14 (WRAMC 7915) Status: Ongoing

Title: Prevention of Gonadal Damage in Women Treated with Combination Chemotherapy or Radiotherapy Below the Diaphragm for Hodgkin's or Non-Hodgkin's Lymphoma.

Start Date:	Est Comp Date:
Principal Investigator: James F. Boyd, M.D., LTC, MC	Facility: DDEAMC
Dept/Svc: Medicine/Oncology-Hematology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results Sep 81 Continue

Study Objective: To determine whether suppression of gonadal function by oral contraceptives in females and by testosterone in males will protect these individuals from subsequent damage to the gonads and sterility as a result of radiation therapy or chemotherapy for the treatment of Hodgkin's disease or non-Hodgkin's lymphoma.

Technical Approach: Pre-treatment, the patients will undergo an endocrine evaluation including baseline LH, FSH, prolactin and estradiol along with menstrual history in females, and in males the baseline studies will include LH, FSH, testosterone and semen analysis. If possible, ovarian biopsy and testicular biopsy will be obtained pre-treatment. The women will be placed on oral contraceptives and the men will be placed on IM-testosterone given on a weekly basis for at least two weeks prior to therapy. The patients will remain on these agents throughout their therapy and at the completion of chemotherapy and/or radiation therapy, their endocrine evaluation will be repeated. Biopsies will not be repeated.

Progress: Due to the lack of eligible patients for this protocol, no individual has been placed on the study from DDEAMC.

Detail Summary Sheet

Date 6 Oct 81	Prot No.: 80-15 (WRAMC 7810)	Status: Ongoing

Title: Prevention of Gonadal Damage in Men Treated with Combination Chemotherapy/ Radiotherapy for Hodgkin's Disease and Non-Hodgkin's Lymphomas. Addendum #1 to WRAMC Protocol 7810.

Start Date:	Est Comp Date:
Principal Investigator: James F. Boyd, M.D., LTC, MC	Facility: DDEAMC
Dept/Svc: Medicine/Oncology-Hematology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results Sep 81 Continue

Study Objective: To prevent permanent infertility and alterations in normal sexual function caused by combination chemotherapy in the treatment of Hodgkin's disease or histiocytic lymphoma. This is to extend WRAMC Protocol 7810 which was limited to Hodgkin's disease and histiocytic lymphoma.

Technical Approach: To study all men ages 18-45 with Hodgkin's disease or non-Hodgkin's lymphoma prior to chemotherapy or infradiaphragmatic irradiation. Patients who have previously received chemotherapy or infradiaphragmatic irradiation will be excluded from this study, as will patients with known history of infertility, chromosomal abnormalities, or prostatic hypertrophy.

Progress: Due to lack of eligible patients for this protocol, no individual has been placed on this study from DDEAMC.

Detail Summary Sheet

Date 28 Sep 81 Prot No.: 80-28 Status: Ongoing

Title: Antimicrobial Therapy in an Animal Abscess Model.

Start Date: Jun 81	Est Comp Date:
Principal Investigator: William L. Moore, Jr., M.D., LTC, MC	Facility: DDEAMC
Dept/Svc: Medicine, Clinical Investigation	Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC Richard W. Harris, CPT, MSC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To develop an appropriate methodology for examination of effects of antibiotics on monomicrobial and polymicrobial abscesses.

Technical Approach: In order to produce an encapsulated virulent strain, all stock organisms studied will be passed through a mouse or rat by s.c. injection with soft agar. The aspirated organism will then be used for rabbit inoculation

Progress: Presently the examination of the ability of Moxalactam to penetrate and kill organisms in an intraperitoneal whiffle-ball abscess is being examined. Initially, penetration of abscess is $\leq$ 7 mg/nl at dose levels of 40 mg/kg a day in 4 kg rabbits, with a decrease of 3 to 4 logs of bacterial population.

Detail Summary Sheet

Date 31 Aug 81	Prot No.: 80-34	Status: Terminated

Title: Correlation of Glycosylated Hemoglobin with Different Degrees of Glucose Intolerance and Possible Standardization of These Values for the Use in the Detection of Diabetes.

Start Date:	Est Comp Date: Aug 81
Principal Investigator: Gildred E. Rivera-Colon, M.D., CPT, MC	Facility: DDEAMC
Dept/Svc: Medicine, Pathology	Associate Investigators: COL Ronny J. Sayers, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To investigate if the determination of glycosylated hemoglobin (GHb) can substitute the Oral Glucose Tolerance Test (O.G.T.T.) in the detection of diabetes and to see if it can be further standardized to be able to differentiate overt diabetes from those with impaired glucose tolerance.

Technical Approach:

Progress: None. Protocol terminated due to PCS of PI.

Detail Summary Sheet

Date 8 Oct 81 Prot No.: 81-30 Status: Ongoing

Title: In vitro Effect of Cimetidine on Herpes Simplex Virus.

Start Date: Indefinite at present		Est Comp Date:
Principal Investigator: David A. Jordan, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Medicine		Associate Investigators: David R. Haburchak, M.D., LTC, MC
Key Words: Cimetidine		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if cimetidine possesses anti-viral activity in vitro.

Technical Approach: Using two known strains each of HSV I and II placque reduction, assays will be performed using various concentrations of cimetidine in the cell culture median. Appropriate controls will also be run. Results will then be determined by the presence or absence of placque reduction in the tubes containing cimetidine. Some idea of antiviral activity in relation to drug concentration will also be gained.

Progress: None. This project has not been started due to principal investigator's responsibilities as an Intern in the Department of Medicine.

Detail Summary Sheet

Date 28 Sep 81 Prot No.: 81-37 Status: Ongoing

Title: Effects of Clostridium difficile Toxin on Ion Transport in Rabbit Ileum and Colon.

Start Date: Sep 81	Est Comp Date:
Principal Investigator: William L. Moore, Jr., M.D., COL, MC	Facility: DDEAMC
Dept/Svc: Medicine, Clinical Investigation	Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC Richard W. Harris, CPT, MSC J.P. Rissing, M.D., VAMC T.B. Buxton, ASCP, VAMC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To examine ion transport in large and small bowel, and changes due to Clostridium difficile toxin.

Technical Approach: To measure electrolytes in a ligated gut loop and the effect of injection of Clostridium difficile toxin into the solution pumped through the loop.

Progress: C. difficile toxin is presently being harvested. Gut loop studies will be conducted after the toxin has been purified and characterized.

Detail Summary Sheet

Date 5 Oct 81	Prot No.: 81-44	Status: Ongoing

Title: Cardiac Rhythm Disturbances Associated with First Dose Exposure to Doxorubicin.

Start Date: Oct 81	Est Comp Date:
Principal Investigator: Gregory G. Friess, D.L., CPT, MC	Facility: DDEAMC
Dept/Svc: Medicine/Cardiology	Associate Investigators: Steve Madden, MD, MAJ, MC Milton D. Alexander, MD, MAJ, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether persons treated with Doxorubicin (Adriamycin) experience cardiac arrhythmias in the 24 hours after initial exposure.

Technical Approach:

Progress: This study approved locally Sep 81, insufficient time to implement during FY 81

Detail Summary Sheet

Date 13 Oct 81 Prot No.: 80-26 Status: Completed

Title: Enhancement of Bonding by Formal Childbirth Preparation

Start Date: Aug 80	Est Comp Date: Nov 81
Principal Investigator: Jane H. Iniety, CPT, ANC	Facility: DDEAMC
Dept/Svc: Nursing	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if there is a difference in the bonding capabilities of mothers who attended childbirth classes vs mothers who did not.

Technical Approach: Observation of first-time mothers during the feeding hour. The time spent with each mother before the observation is about 30 minutes to one hour. Then the mothers are observed and according to the scale, scores are given on their bonding behavior towards their babies.

Progress: This study was completed; however, principal investigator PCS'd and did not turn in a final report.

Detail Summary Sheet

Date 18 Aug 81	Prot No.: 80-32	Status: Completed

Title: The Effect of Specific Instructional Objectives on Students' Retention.

Start Date: Sep 80		Est Comp Date: Jan 81
Principal Investigator: Lawrence J. Eberlin, MAJ, ANC		Facility: DDEAMC
Dept/Svc: Nursing		Associate Investigators:
Key Words: Retention		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To investigate the benefits of informing students of the instructional objectives. Since there seems to be conflicting evidence concerning all aspects of behavioral objectives, it was decided to restrict this investigation to a basic question, namely, will behavioral objectives help to improve the students' retention?

Technical Approach: Subjects were students enrolled in the Patient Care Specialist Course at DDEAMC. One class was the control group, the following class was the experimental group. Control group received list of specific instructional objectives for the subject matter, the experimental group was not given the list. Both groups received the same 23 hours of lecture. A comprehensive, objective type test was given 12 weeks after the completion of the subject matter. The test was used to evaluate the students' retention.

Progress: The results do not substantiate the hypothesis that giving the student a list of specific instructional objectives will have an effect on the students' retention. No definite conclusions can be drawn from this study of 57 students. There does seem to be support for the findings that use of objectives has no significant effect on students' retention. It is difficult to make generalizations because of a lack of consistent operational definitions and because of the equivocal nature of the studies done thus far. There is a need for the operational definitions to be consistent and then carry out several studies.

Detail Summary Sheet

Date 14 Oct 81 | Prot No.: 80-33 | Status: Completed

Title: Touch in Nursing: Relationship of Values to Selected Characteristics in Nurses.

Start Date: Oct 80	Est Comp Date: Nov 80
Principal Investigator: Jimmie R. Williams, R.N., B.S.N.	Facility: DDEAMC
Dept/Svc: Nursing	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To acquire additional information in the possible meanings of touch to different individuals and how touch may be used most effectively as a separate nursing care measure.

Technical Approach: The investigator will conduct each interview using the "Interview Schedule, Use of Touch" developed for this study. Forty military registered nurses currently working at DDEAMC will be interviewed. Subjects will be between the ages of 22-35 years, be native born USA citizens, have completed a minimum of a baccalaureate degree in nursing, and have a minimum of two years military nursing experience. These 40 nurses will be divided into two equal groups of 20 male and 20 female nurses.

Progress: The great majority of registered nurses state that they regard the use of non-procedural touch as highly or moderately therapeutic (value touch). A substantial majority of nurses report that they use non-procedural touch frequently in nursing care. The memory of being touched frequently in their childhood years is related to registered nurses' reported use of non-procedural touch in nursing care. Since no relationship is found between the value or use of touch and the sex of registered nurses, gender related differences may not constitute a fruitful area of research among nurses. The majority of nurses of both sexes do not perceive themselves as using touch differently with patients of the opposite sex.

Detail Summary Sheet

Date 13 Oct 81 Prot No.: 81-8 Status: Completed

Title: A Comparison of Two Anesthesia Circuits.

Start Date: Dec 80	Est Comp Date: Sep 81
Principal Investigator: Roy Patrick, CPT, ANC	Facility:
Dept/Svc: Nursing/Anesthesiology Nursing Course	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare a simple and safe anesthesia breathing system -- the Bain's Circuit with the semi-closed circle CO_2 absorber system.

Technical Approach: The two anesthesia circuits were compared as to the degree of pulmonary function impairment caused by each.

Progress: It is concluded from this study that the Bain's Circuit and the Circle CO_2 absorber circuit are no different in terms of their lasting effects on the human pulmonary system as measured by sO_2. A future study where the Bain's Circuit and the Circle CO_2 absorber circuit are interchanged back and forth on an anesthetized patient and sO_2 measurements made at each change is recommended. Such a study could demonstrate any differences in effects to the pulmonary system between the two circuits while in actual use.

Detail Summary Sheet

Date 2 Oct 81	Prot No.: 81-9	Status: Completed

Title: A Comparison of Butarphanol Tartrate and Morphine Sulfate as Pre-Anesthetic Medications.

Start Date: Dec 80	Est Comp Date: Sep 81
Principal Investigator: Henry J. Walker, CPT, ANC	Facility: DDEAMC
Dept/Svc: Nursing/Anesthesiology	Asscciate Investigators: Daniel J. Geniton, CPT, ANC
Key Words:	Peter P. Price, LTC, ANC

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the utilization of Stadol with Morphine as a preoperative medication.

Technical Approach: Forty-six patients were randomly selected after written consent was obtained. Twenty-three patients were assigned to the Morphine (control) group and twenty-three patients were assigned to the Stadol group. The parameters studied in each group included pre and post treatment blood pressure, pulse and respiration. The degree of sedation, nausea and vomiting and apprehension post administration of drugs were also studied. Data was analyzed using the students paired t-test and two sample t-tests. All data was considered at the level of significance of $p<0.05$.

Progress: There were no significant differences noted in any of the six parameters studied. We found Stadol to be as effective in comparison with Morphine when used as a premedicant. Study has been completed.

Detail Summary Sheet

Date 13 Oct 81	Prot No.: 81-10	Status: Terminated

Title: Liver Enzyme Changes in Nurse Anesthetists Prior to and at Six and Twelve Months After Initial Exposure. Does the Operating Room Environment Present an Hazard?

Start Date:	Est Comp Date: Sep 81
Principal Investigator: Kenneth Duggan, CPT, ANC	Facility: DDEAMC
Dept/Svc: Anesthesiology Nursing Course	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To quantify the occupational risk of an operating room environment to 31 Army Nurse Corps Officers upon exposure to operating room environment.

Technical Approach:

Progress: Due to PCS of principal investigator, study was not started.

Detail Summary Sheet

Date 14 Oct 81 | Prot No.: 81-11 | Status: Completed

Title: Military Primigravidas' Learning Response to Group versus Individual Discussion of Infant Growth and Development.

Start Date: Jan 81	Est Comp Date: Sep 81
Principal Investigator: Nona A. Yeager, R.N.	Facility: DDEAMC
Dept/Svc: Nursing	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To ascertain if there is a difference in learning of primiparas presented with two-week Well Baby Clinic information either in a group situation or on one-to-one basis and to see if the learning may be influenced by their prior level of knowledge of growth and development.

Technical Approach: A group of 40 primigravidas were seen on the postpartum ward and interviewed for inclusion into study. An appointment was given after they filled out a pre-test and was on a random basis. The mothers and children were seen at 10 - 21 days and taught according to their random selection in group or individually. A post-test was given at the two month checkup. About 6 - 8 patients were lost to followup of the 40. Data collection was completed in June.

Progress: Currently, data is under analysis and preliminary results indicate no difference between their learning. Also, the prior learning modifying factor influenced amount learned, but not differently, based on the group or individual situation.

Detail Summary Sheet

Date 5 Oct 81	Prot No.: 81-36	Status: Ongoing

Title: The Use of Volume Capacity Determinations of Intermittent Infusion Reservoirs as a Guideline for Maintenance Solution Flushes.

Start Date: Aug 81	Est Comp Date: Jan 82
Principal Investigator: Terry A. Newton, 1LT, ANC	Facility: DDEAMC
Dept/Svc: Nursing	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective:

1. Determine the volume capacities of the various Intermittent Infusion Reservoirs stocked at DDEAMC.
2. Compare and contrast volume capacities between over-the-needle and winged tipped heparin locks.
3. Determine the amount of heparin flush solution used by nursing personnel in maintaining the patency of heparin locks on a daily basis.
4. Develop nursing guidelines for maintaining heparin locks.

Technical Approach:

The data gathered in the first part of the investigation (1 and 2 above) will be used to set guidelines for the maintenance of heparin locks at DDEAMC.

The data collected in the second part of the investigation (3 and 4 above) will be compared to the data collected in the first part and conclusions concerning current practice without guidelines will be made.

Progress: All IV catheters stocked at DDEAMC and capable of being converted to a heparin lock of the over-the-needle and winged tipped types were checked for volume capacity. For over-the-needle catheters, the volume capacities ranged from .08cc to .18cc. For winged tipped catheters, the volume capacities ranged from .18 to .56cc. It was found that the prepackaged heparin locks had, without exception, the lowest volume capacities for their catheter type.

Data collection for Objective #2 and more detailed analysis of the data collected to date will begin in October 1981.

Detail Summary Sheet

Date 5 Oct 81 | Prot No.: 81-41 | Status: Ongoing

Title: The Relationship of Job Satisfaction and Empathic Ability Among Hospital Staff Registered Nurses.

Start Date: Oct 81	Est Comp Date: Apr 82
Principal Investigator: Cathy J. Johnson, CPT, ANC	Facility: DDEAMC
Dept/Svc: Nursing	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To examine the relationship of job satisfaction and empathic ability among staff nurses working in a hospital setting.

Technical Approach:

Progress: This study locally approved in Sep 81, insufficient time to implement during FY 81.

Detail Summary Sheet

Date 18 Aug 81 Prot No.: 80-17 Status: Completed

Title: The Prophylactic Use of Doxycycline and Cephamandole in Women Undergoing Vaginal Hysterectomy.

Start Date: Feb 80	Est Comp Date: Jun 81
Principal Investigator: Gary B. Broadnax, D.O., LTC, MC	Facility: DDEAMC
Dept/Svc: Obstetrics-Gynecology	Associate Investigators:
Key Words: Prophylactic antibiotics	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the efficacy of prophylactic doxycycline or cephamandole in reducing the incidence and severity of postoperative infectious morbidity in pre-menopausal women undergoing vaginal hysterectomy.

Technical Approach: A prospective randomized, comparative, third-party blinded in pharmacy study was conducted on all patients undergoing vaginal hysterectomy between February 1980 and June 1981.

Progress: Thirty-eight patients completed the study. No significant conclusions are warranted from this number of patients.

Detail Summary Sheet

Date: 26 Oct 81	Prot No.: 80-23	Status: Ongoing

Title: Evaluation Study on Sulfamethoxazole-Trimethoprim Lactate in 5% Sheep Blood Agar Plate. (Children)

Start Date: Oct 80		Est Comp Date:
Principal Investigator Charles L. Lamke, LTC, MSC		Facility: DDEAMC
Dept/Svc: Pathology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the percentage of beta hemolytic streptococci isolated from a normal pediatric population utilizing the standard procedures versus the use of the selective SXT media.

Technical Approach: Approximately 100 normal pediatric patients will be utilized in this study and the results will be evaluated.

Progress: Unable to obtain report from principal investigator. Protocol will be reviewed by IRC in Jan 82, recommendation will be to terminate study.

Detail Summary Sheet

Date 1 Oct 81	Prot No.: 81-23	Status: Terminated

Title: Immunofluorescent Identification of Anti-Progesterone Antibodies in Human Serum.

Start Date: Apr 81	Est Comp Date: Sep 81
Principal Investigator: Janet H. Riggsbee, MT, DAC	Facility: DDEAMC
Dept/Svc: Pathology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To detect anti-progesterone antibodies by the use of immunofluorescence techniques.

Technical Approach: An indirect or sandwich technique for immunofluorescent identification of serum antibodies was used, following standard techniques in Serology.

Progress: Rabbit ovary was the substrate used by the original investigator. As back up substrates, rat ovary and monkey ovary were used as well as the rabbit ovary due to the questionable reactivity of the female rabbit ovary available at this institution. Concerning the immunofluorescent procedure, two types of antisera labeling was used. The first involved a rabbit antihuman serum and FITC labeled anti-rabbit IgG, and the second required FITC antihuman immunoglobulins. Variable dilutions of the patient's serum samples as well as undiluted patient's serum were tested on all three substrates with both labeling techniques. No specific fluorescence of the cells of the corpus luteum was observed. The acceptability of the substrate could not be determined, although some staining occurred with antiprogesterone rhodamine labeled antiserum. This antiserum is intended for use on human breast tissue for the identification of progesterone receptor sites and may have no validity in this context. At this time no alternatives for continuation of this study are available unless answers to several areas of difficulty can be supplied. Did substrates used provide sites for antibody attachment of progesterone antibodies? Was labeling system sensitive and specific for antibody being tested? Could patient be negative for this antibody, (no positive control available)? Or, at time of sampling could the patient's antibody have been too low to detect due to treatment?

Detail Summary Sheet

Date 28 Sep 81 Prot No.: 81-35 Status: Ongoing

Title: Comparative Study of API-20E, Micro-Scan and Micro-ID Methods of Identification of Enterobacteriaceae.

Start Date: Oct 81	Est Comp Date:
Principal Investigator: Pablo M.S. Lomangcolob, M.D., MAJ, MC	Facility: DDEAMC
Dept/Svc: Pathology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Revie Results

Study Objective: To determine the best suitable method to use at DDEAMC for the identification of Enterobacteriaceae by comparing cost and accuracy of API -20E, Mirco-Scan and Micro-ID methods.

Technical Approach: Identification of fresh clinical isolates and stock organisms by the three methods mentioned above. Agreements and disagreements are recorded and statistical comparisons made. Cost of time and materials will be analyzed for each method.

Progress: Project will be started 15 October 1981. It could not be started sooner due to: 1) Familiarization by researcher and involved medical technologists of the Bacteriology Section with both the Micro-ID and Micro-Scan methods, adequate familiarization time estimated at 2-4 weeks; 2) Time required to fill the order for enough consumable supplies needed for the project.

Detail Summary Sheet

Date 1 Oct 81	Prot No.: 81-32	Status: Ongoing

Title: A Comparative Study of Immunofluorescence in Fresh Frozen and Paraffin-Embedded Skin Tissue.

Start Date: Jun 81		Est Comp Date:
Principal Investigator: Janet H. Riggsbee, MT, DAC		Facility: DDEAMC
Dept/Svc: Pathology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To confirm the results of previous investigators, to develop a reliable technique for the processing of paraffin-embedded skin tissue, and to investigate the demonstration of complement deposits in paraffin-embedded skin tissue of patient's with certain auto-immune skin disorders.

Technical Approach: In patients suspected of having autoimmune disease, biopsies are routinely taken for immunofluorescent studies and H&E sections. Some of the remaining paraffin-embedded tissue will be processed according to various methods that we establish and stained by immunofluorescence antisera.

Progress: Preliminary studies of various enzymatic digestion techniques on human paraffin-embedded tissue have been completed, with satisfactory results, although further study is currently taking place. Several tissue samples are currently under study, no data is presently available.

Detail Summary Sheet

Date 6 Oct 81	Prot No.: 81-20	Status: Ongoing

Title: Steroid Receptor Status of Cells Grown in Tissue Culture Started From Human Malignant Stem Cells.

Start Date: Apr 81		Est Comp Date:
Principal Investigator: Cherry L. Gaffney, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Pathology, Medicine, Clinical Investigation		Associate Investigators: James F. Boyd, M.D., MAJ, MC James C. McPherson III, PhD, DAC Robert W. Prior, MT, DAC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To establish clones from individual malignant stem cells, preferably from breast cancers, and to determine estrogen and progesterone receptor status of numerous clones as well as the individual cells within the clones.

Technical Approach: Harvesting cells from malignant effusions, separating out the tumor cells, and planting the tumor cells in semi-solid cell culture. Estrogen and progesterone receptor status will be determined by a fluorescent stain recently marketed by Zeus which we are investigating in Protocol No. 81-21.

Progress: Presently testing out harvesting techniques. When an effusion is bloody and the relative number of tumor cells is small, regular centrifugation has failed to be adequate. We have attempted to separate out tumor cells by using nucleopore filters and subsequently planting the filters. The cultures were overgrown by Aspergillus and there has been no appropriate subject since that time. If nucleopore filter fails to meet our needs, we will utilize ultracentrifugation.

A lab at the Augusta VA Hospital is using a cell culture technique very similar to ours, and we have arranged for two members of our team to train there for a week to improve our cell culture technique and, thus, hopefully, avoid fungal contamination without resorting to cellular poisons.

Detail Summary Sheet

Date 20 Oct 81	Prot No.: 81-22	Status: Ongoing

Title: Immunopathological Identification (Classification) of Lymphomas.

Start Date: Nov 81	Est Comp Date:
Principal Investigator: Mark C. Anderson, D.O., CPT, MC	Facility: DDEAMC
Dept/Svc: Pathology	Associate Investigators: Janet Riggsbee, MT, (ASCP), DAC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To develop an aid in the diagnosis and evaluation of human lymphomas for routine use on biopsy specimens.

Technical Approach: Old cases, using paraffin sections will be studied first to evaluate the immunofluorescent technique. From all biopsy lymphnode material, a sampling will be snap-frozen and stored at -70°C. Immunofluorescent testing with various antisera will be performed on each biopsy and results recorded by technologist and analyzed by pathologist. Correlation of other histological procedures and data and resulting diagnosis is the responsibility of the pathologist.

Progress: Original principal investigator PCS'd before starting study. A new investigator has just taken over project; therefore, no progress has been made.

Detail Summary Sheet

Date 16 Oct 81 Prot No.: 81-21 Status: Ongoing

Title: An Evaluation of the Fluorescent Cytochemical Detection of Steroid Receptor Positive and Negative Cells in Human Breast Carcinoma.

Start Date: May 81	Est Comp Date:
Principal Investigator: Cherry L. Gaffney, M.D., CPT, MC	Facility: DDEAMC
Dept/Svc: Pathology	Associate Investigators: Janet Riggsbee, MT
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: There is a new method of determining estrogen and progesterone receptor (ER-PR) status of tissue by use of fluorescent cytochemistry. We are using Zeus Chemicals' newly marketed "Fluorocep" stain. Our study is designed to evaluate our correlation between Fluorocep staining results and the conventional cytosol method results. We are also evaluating reproducibility of results.

Technical Approach: All malignant breast tumors biopsied in our hosptial are being evaluated by Fluorocep staining for estrogen and progesterone receptors on the diagnostic frozen section and on a portion of the tissue that is sent to Upjohn for cytosol ER-PR determination. Results will be correlated after sufficient specimens have been evaluated. Unstained frozen sections of breast biopsies are being exchanged with a pathologist at University Hospital, Augusta, GA for Fluorocep staining by both of our labs and results are being exchanged. Results will be correlated after sufficient specimens have been evaluated.

Progress: A procedure has been established and is in current practice in the Anatomic Pathology Section for routine submission of tissue from breast biopsies to our Immunology Section for staining. We have gathered 31 cases from our surgical specimens, all of which have also been sent to University Hospital and, when sufficient tissue has been available, to Upjohn. Results are being recorded. We have received unstained slides from 17 cases from University Hospital as well as subsequent cytosol and staining results from their lab.

Detail Summary Sheet

Date 21 Oct 81	Prot No.: 81-33	Status: Ongoing

Title: Evaluation of the Roche Laboratory Isomune LD-1 and Isomune CK-MB Test Kits as Compared to the Helena Laboratories CPK, LDH Isoenzyme Techniques in the Diagnosis of Acute Myocardial Infarction.

Start Date: Jul 81	Est Comp Date:
Principal Investigator: Mark C. Anderson, D.O., CPT, MC	Facility: DDEAMC
Dept/Svc: Pathology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: A comparison of the Helena and Roche methods of isoenzyme analysis to ascertain the following: a) Ability of each test to discriminate between disease and non-disease states; b) Time required for diagnostic profile completion for each methodology.

Technical Approach: Perform routine isoenzyme (Helena methodology) analysis on all patients admitted to MICU for chest pain. Select 25 patients having diagnostic criteria for acute myocardial infarction and choose 25 people admitted for chest pain, but lacking EKG changes and having no evidence of enzyme elevations. On these 50 patients perform the Roche CPK-MB and LDH-1 tests on their routine specimens. This population will be used to make the analysis described in the objectives above.

Progress: No reportable data available.

Detail Summary Sheet

Date 15 Oct 81 Prot No.: 79-17 Status: Completed

Title: Incidence of PCP-Related Psychosis.

Start Date: Aug 80	Est Comp Date: Apr 81
Principal Investigator:	Facility:
William E. Logan, M.D., LTC, MC	DDEAMC
Dept/Svc:	Associate Investigators:
Psychiatry & Neurology	Michael B. Vandewalle, M.D., MAJ, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the incidence of exposure to PCP in patients admitted to the DDEAMC Inpatient Psychiatry Service and the incidence of PCP-related psychosis.

Technical Approach: Urine screen for PCP on all patients admitted over a four month period (approximately 200 cases).

Progress: This study examined the incidence of PCP psychosis, as determined by urine screening. Of 228 psychiatric admissions, only one patient was found to be positive for PCP. This suggests that the incidence of PCP psychosis in this population is very low. However, it does occur as evidenced by the one positive patient who appeared schizophrenic but recovered quickly with only supportive therapy. Routine urine screening can assist in diagnosis and should always be included in the evaluation of suspected cases, especially in clinical studies of this entity.

Detail Summary Sheet

Date 21 Oct 81	Prot No.: 80-10	Status: Completed

Title: Investigation of Patient Non-Compliance: Failure to Claim Turned-In Cost-Free Prescriptions.

Start Date: March 80	Est Comp Date: Sep 81
Principal Investigator:	Facility:
William G. Bissell, M.D., MAJ, MC	DDEAMC
Dept/Svc:	Associate Investigators:
Psychiatry & Neurology, Pharmacy	LTC Sam Shannon, Jr, MSC
Key Words:	Willie Patterson, M.D.

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: The explication of those factors important in the etiology of patient non-compliance in a cost-free health care system.

Technical Approach: This study utilized a unique population of patients known to be 100% non-compliant with their prescribed medical regimen. This non-compliance was unrelated to cost to the individual. Data was gathered via questionnaire on factors which might have contributed to this non-compliance. The doctor-patient relationship was an area of particular focus. A list of patients who failed to pick up turned-in prescriptions was compiled by the Pharmacy for March, April and May 1980. These individuals, along with a control sample who did pick up prescriptions during the same time frame, were mailed questionnaires and return envelopes.

Progress: The data collection and most statistical analysis is completed, but have not reached final conclusions.

Detail Summary Sheet

Date 15 Oct 81	Prot No.: 80-11	Status: Ongoing

Title: Increasing Hypertensive Regimen Compliance by Teaching Doctor-Patient Negotiations.

Start Date: Jan 81	Est Comp Date:
Principal Investigator: William G. Bissell, M.D., LTC, MC	Facility: DDEAMC
Dept/Svc: Psychiatry & Neurology, Family Practice	Associate Investigators: Gregory D. Aeschliman, M.D., CPT, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results May 81 Continue

Study Objective: The objective is to attempt to develop a cost-effective method of improving hypertensive regimen compliance by utilizing a videotape presentation to teach both doctors and patients better methods of communication.

Technical Approach: A videotape has been produced that shows typical doctor-patient interactions and then specific ways in which the doctor and the patient can facilitate better communications. This tape will be shown to groups of Family Practice patients who are being treated for hypertension and to their Family Practice physicians. Some groups will have a group discussion after the film, others will not. Together with control groups, a three by three study will be done with nine groups of patients. Parameters such as systolic and dyastolic B.P., body weight, and amount of medication will be analyzed for all groups.

Progress: This project is currently not being worked on secondary to a current lack of time available to the investigators. This situation will hopefully be alleviated by July 1982, if a Family Practice physician is selected as a Psychosomatic Medicine Fellow.

Detail Summary Sheet

Date 15 Oct 81 Prot No.: 80-12 Status: Ongoing

Title: Development of a Scale to Predict Trainee Failure in the Army.

Start Date: Nov 80	Est Comp Date:
Principal Investigator: William G. Bissell, M.D., LTC, MC	Facility: DDEAMC
Dept/Svc: Psychiatry & Neurology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review: May 81 Results Continue

Study Objective: To develop a cost-effective easily administered screening examination to identify those trainees who will subsequently not be able to complete training due to emotional immaturity.

Technical Approach: A set of 148 questions has been developed which assesses specific ego functions which are necessary to successfully complete military training. Deviation from normal scores is hypothesized to be predictive of subsequent failure.

Progress: This project has made no progress during the last year secondary to a lack of interested personnel. The project is currently being considered by several psychiatric residents. It is hoped that they might be sufficiently interested to complete the project.

Detail Summary Sheet

Date 18 Aug 81	Prot No.: 80-19	Status: Completed

Title: Pain Relief and Return of Function Following Surgery: A Comparison of Predictors.

Start Date: Feb 80		Est Comp Date: Feb 81
Principal Investigator: John J. Treanor, M.D., COL, MC		Facility: DDEAMC
Dept/Svc: Neuropsychiatry		Associate Investigators: John McCormack, PhD, LTC, MSC Andree Lloyd, PhD, VA Med Ctr Walter Piskun, MD, LTC, MC
Key Words: Predictors LBP (Low Back Pain) Neurosurgery Pain Surgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare selected predictors of outcome of neurosurgical intervention for relief of low back pain (LBP).

Technical Approach: Candidates for surgery were evaluated by the principal investigator prior to surgery. Evaluation consisted of an anamnestic history, mental status exam, and the HENDLER SCREENING TEST. The MMPI and Beck Depression Index were evaluated pre-operatively. The operating surgeon provided a weighted scale based on pre-operative physical findings, EMG and myelogram as well as a description of operative findings. A simple questionnaire was administered by the principal investigator approximately six months after surgery to evaluate relief of pain and/or return of function.

Progress: Hendler questionnaires were administered to 29 patients. Surgery was performed on 15 of these patients. Psychometric testing was completed on 12 of the 15. Six-month post-operative questionnaires were completed on all 15. Dr. Piskun (Neurosurgeon) departed and the new neurosurgeon desired to discontinue the study. Data was tabulated and compared with an attempt to "quantify" scores for MMPI, ISB and Beck Scale on 12 of the cases. Cut-off scores for the Hendler were compared. Best Hendler cut-off score was 18. Sample size of 15 was too small to make predictive inferences. Estimated sample minimum size would be 76.

Detail Summary Sheet

Date 15 Oct 81	Prot No.: 80-24	Status: Completed

Title: Modification of Attitudes Toward Women in the Army/The Male-Female Soldier Team.

Start Date: Jul 80	Est Comp Date: Dec 80
Principal Investigator: Victor C. Bell, M.D., CPT, MC	Facility: DDEAMC
Dept/Svc: Psychiatry & Neurology	Associate Investigators:
Key Words: Women soldiers	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To measure effect of small-group activities in leadership training with a focus on male-female relationships and attitudinal change concerning the role of males and females in the US Army.

Technical Approach: Small group therapy techniques: Selected NCO's were enrolled in small groups of six to eight individuals and participated for eight weekly sessions of discussion and evaluation. The focus of the weekly sessions was two-fold. To teach methods of attitudes toward women in the armed services.

Progress: Changes in attitudes toward women in the Army occurred in a positive (i.e., more accepting) way. The change, however, was not statistically significant when compared to a sample of peers not enrolled in the study groups. Some methodological errors may have contributed to the lack of statistical significance. It is felt that the technique has wider application to other Army units.

Detail Summary Sheet

Date 28 Sep 81 Prot No.: 80-27 Status: Completed

Title: Study of Herpes Simplex Virus I Antibodies in Recently Admitted Psychiatric Patients.

Start Date: Oct 80	Est Comp Date: Jul 81
Principal Investigator: Matthew E. Levine, LTC, MC	Facility: DDEAMC
Dept/Svc: Psychiatry, Pathology	Associate Investigators: Paul Trainor, DAC
Key Words: Depression Herpes Simplex I	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Revie Results

Study Objective: To obtain serum antibody titers to Herpes Simplex Virus I of psychiatric inpatients for comparison to non-psychiatric serum levels and correlation to various psychiatric diagnostic parameters.

Technical Approach: All patients admitted to the psychiatric wards (3 wards with a bed capacity of 100, and an average daily census of 73.6) of the DDEAMC will be screened for the presence of antibodies to HSV-I virus. Screening will be done by means of the Indirect Fluorescent Antibody Test at dilutions of 1:8 and 1:32, and further if antibody is found to be present.

Progress: A paper titled "Depression in Psychiatric Admissions to a Military Medical Center", has been accepted for publication in Military Medicine. The report was compiled in conjunction with this Herpes/Depression project as an unexpected finding. Work is continuing on the Herpes/Depression data in an attempt to define the relationship.

Detail Summary Sheet

Date 14 Oct 81 Prot No.: 81-15 Status: Ongoing

Title: The Impact of Individual Counseling Reorganization in an Inpatient Psychiatric Melieu.

Start Date: Feb 81	Est Comp Date:
Principal Investigator: Charles S. Burke, M.D., CPT, MC	Facility: DDEAMC
Dept/Svc: Psychiatry & Neurology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: a) To study the effect that different requirements for individual counseling would have on the attitudes of patient groups. b) Assess the impact the different approaches would have on staff performance.

Technical Approach: The project was scheduled to study a six-month period of time on three wards consisting of five teams: three control, two experimental. The Ward Atmosphere Scale (WAS) was used to assess patient and staff attitudes, twice prior to the implementation of the new counseling requirements on the experimental wards and four times afterwards.

Progress: The above noted measurements have been obtained over the six-month period and presently are being processed for statistical significance and graphic analysis.

Detail Summary Sheet

Date 19 Aug 81	Prot No.: 81-24	Status: Completed

Title: Depression in Psychiatric Admissions to a Military Medical Center.

Start Date: Mar 81	Est Comp Date: Jun 81
Principal Investigator: Matthew E. Levine, M.D., LTC, MC	Facility: DDEAMC
Dept/Svc: Psychiatry & Neurology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To assess the frequency and severity of depression in newly admitted psychiatric patients and to correlate this with clinical diagnosis and disposition.

Technical Approach: Two hundred consecutive admissions to the 3-ward Psychiatric Unit at DDEAMC were screened for depression by means of the 21 Item Beck Depression Inventory.

Progress: Thirty-six patients in the 15 to 19 year-old range had a mean score very closely approximating that of severe depression, and exceeding that of a group of suicide attempters in another published report. The 19 year-olds were the most depressed of the under 30 group. The findings confirm previous impressions that severe depression in adolescence is frequent and may be overlooked, possibly due to over-reliance on unproven theoretical assumptions.

Detail Summary Sheet

Date 15 Oct 81	Prot No.: 81-34	Status: Ongoing

Title: Dexamethasone Suppression Test (DST) in Depression; Clinical and Psychological Correlates and Response to Tricyclic Antidepressants (TCA).

Start Date: Jul 81	Est Comp Date: Jun 82
Principal Investigator: Andrea C. Bradford, M.D., CPT MC	Facility: DDEAMC
Dept/Svc: Psychiatry & Neurology	Associate Investigators:
Key Words: Depression Dexamethasone	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) Test efficacy of DST in diagnosing major depression; 2) determine whether there are a subset of patients with cortisol hypersecretion and normal DST; 3) determine whether or not there are correlates in family history, psychological test results or response to desipramine or amitriptyline to hypersecretion of cortisol, response to DST or timing of escape from cortisol suppression; 4) determine whether or not cortisol hypersecretion and abnormal DST correct on recovery.

Technical Approach: 1) Baseline 24-hour urine for free cortisol, 0800 and 2300 serum cortisol, psychological testing, depression scales, family history; 2) 1 mg dexamethasone at 2300 followed by 0800, 1600, and 2300 serum cortisols; 3) treatment with tricyclic desipramine or amitriptyline (double-blind) daily depression checklist, weekly depression scales; 4) after four weeks, or upon clinical remission of depression, repeat baseline studies.

Progress: Three patients entered into protocol, ongoing collection of data.

AD-A108 139 DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER FORT GOR--ETC F/G 6/5
CLINICAL INVESTIGATION PROGRAM REPORT.(U)
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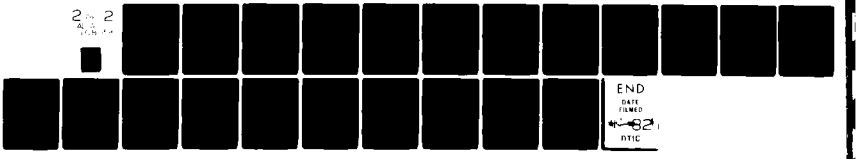

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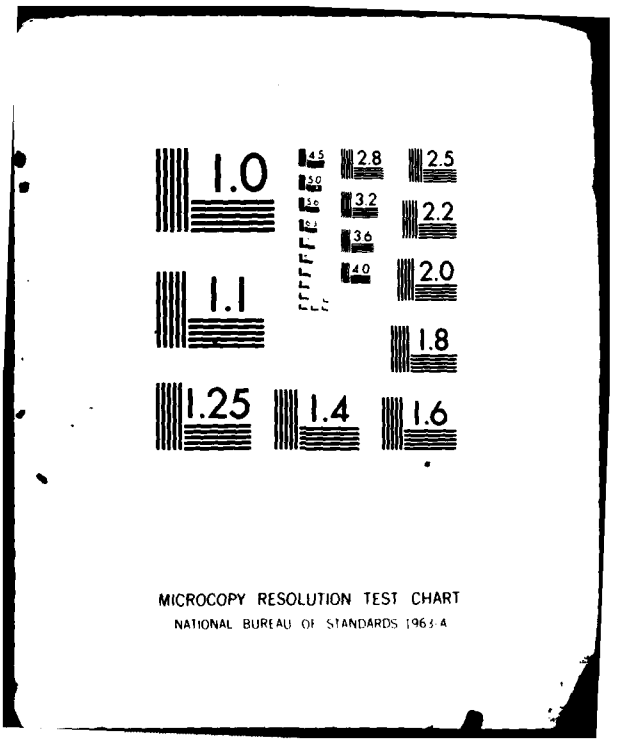
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Detail Summary Sheet

Date 5 Oct 81	Prot No.: 81-29	Status: Completed

Title: Demographic Profile of Child Maltreatment Cases Referred to DDEAMC Child Protection and Case Management Team.

Start Date: May 81	Est Comp Date: Aug 81
Principal Investigator: Penny Stauffer, Graduate Student	Facility: DDEAMC
Dept/Svc: Social Work Service	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To describe child maltreatment cases by selected variables, and to identify predominant characteristics which may be key factors in families where children are maltreated and indicate those families at high risk of child abuse and/or neglect.

Technical Approach: This study utilized a retrospective, record review method to describe the characteristics of child maltreatment among military families reported to the Child Protection and Case Management Team (CPCMT) at DDEAMC, Fort Gordon, during a ten-year period, January 1971 through December 1980. All of the case files during the ten-year period were reviewed and selected variables were identified and recorded when available. The data were coded and keypunched onto cards in order to utilize the computer at the Department of Clinical Investigation, DDEAMC. Descriptive statistics were used to summarize the observations made on each variable for the total population of child maltreatment cases and for each of the three sub-categories, namely, child abuse cases, child neglect cases, and involving both child abuse and child neglect. The descriptive statistics included frequency distributions, indexes of central tendency and indexes of dispersion.

Progress: In view of the findings, the military family in which child maltreatment occurred was most likely to be one of a Caucasian, active duty soldier in one of the enlisted grades, E4 - E7, who was married, living with his spouse, and experiencing marital discord. Both parents were likely to be 20 to 34 years old. They were likely to have one or two children who were biologically related and less than six years old. The first born child was the most likely to be either abused by the father or neglected by the mother. The abuse was most likely to result in bruises and the neglect was most likely to involve physical neglect and/or lack of adequate supervision. A maltreatment incident in the family was most likely to be reported only once to the CPCMT and was most likely a new case at DDEAMC. The findings show a wider range of substantial numbers of cases involving children over the age of three years than earlier published studies of child maltreatment among military families. In addition, the findings show a substantial number of cases were distributed over a wider range of ages of the parents and the grades of the sponsors, when compared to previously published studies. In a military setting, command control and discipline are important, health care is likely to be utilized

(Continued)

because it is econimically affordable to all, and military health care providers are typically not reluctant to confront suspected child maltreatment. Therefore, it is assumed that the majority of child maltreatment incidents that do actually occur in military families are identified, reported, and treated. In light of these active case-finding efforts, the findings in this study, based on reported cases, most likely depict the actual frequency of child maltreatment occurring in the military. Intervention in child maltreatment cases was very likely to entail a number of different professionals from different disciplines at DDEAMC who made multiple family and collateral contacts. In addition, there were likely to be two or three other civilian or military agencies involved in each case. This inter-disciplinary, multi-agency effort requires a great amount of case coordination and cooperation among all of the personnel involved. Overall, it appears that the military at DDEAMC and Fort Gordon have made a significant and recognizable effort to deal with child maltreatment problems among military families. Over the ten-year period, there was a very low percentage of cases resulting in the death of a maltreated child when compared with all of the previously published studies that were reviewed. The low rate of recidivism that was found suggests that the majority of families returned to a stable level of functioning and learned to deal with stresses in other ways. The high percentage of cases in which the child remained in his/her own home with the provision of protective services indicates that the military service health care providers have helped to strengthen the capacity of many families to parent their children without resorting to maltreatment.

Detail Summary Sheet

Date 1 Nov 1981 Prot No.: 78-14 Status: Ongoing

Title: Intraocular Lens Study

Start Date: May 1978	Est Comp Date:
Principal Investigator: Walter T. Spelsberg, M.D., LTC, MC	Facility: DDEAMC
Dept/Svc: Surgery/Ophthalmology	Associate Investigators: Tonya Pavlovic, M.D., CPT, MC
Key Words: Intraocular Lens, Implant, Ophthalmology, Aphakia, Surgery	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results Continue

Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.

Technical Approach: Currently accepted surgical techniques for cataract extraction and intraocular lens implantation using the operating microscope.

The study is also going to be concerned strictly with the use of Intraocular cataract extraction with use of the Anterior Tennant-Choyce Implant.

Progress: Since the start of this study at DDEAMC in September of 1980 there have been close to seventy (70) Anterior Chamber Intraocular Lenses implanted. Of all the patients implanted, final visual acuities have been no worse than 20/40 in the operated eye. Of the seventy (70) patients, only ten (10) had even minor complications and no one had a major complication such as a rupture capsule, avitreous loss, a prolonged iritis, or any situation necessitating a removal of the implant.

Most of our patients are so satisfied they want secondary implants in their other eye. Further, most patients have enjoyed 20/20 vision or better and because of our over correction method, they are actually seeing small print even better than before their cataracts.

At the present time, A-Scan ultra sonography is used to determine axial length in all patients preoperatively. In addition, the Texas Instrument computer is used to calculate the power in the patient with the Binkhorst method using a minus 2.000 dioptric correction preoperatively in order to obtain better vision for the cells in retina. By this, we mean that the image on the retina is enlarged to the point where the objects are seen more clearly both at distance and near. Of course, most patients still need corrective lenses for reading material just as prior to their cataracts.

Detail Summary Sheet

Date 1 Sep 81	Prot No.: 81-27	Status: Ongoing

Title: Computer-Assisted Surgical Instruction.

Start Date: May 81		Est Comp Date:
Principal Investigator: Fred H. Edwards, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Surgery		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To provide a means of surgical instruction that can be used at the convenience of the student.

Technical Approach: The Hewlett-Packard 9830A computer will be used. A series of general topics will be selected by the surgical staff. The programmer will develop clinical situations stressing major concepts pertaining to each topic. After reviewing the proposed clinical situations with the staff, the programmer will translate the situations into a computer program. This program can then be stored on a magnetic tape file for future use.

Progress: Presently the computer system is being transferred to the HP 9845. This is a more sophisticated computing device with CRT (cathode ray tube) capability and should prove more suitable for an instructional system.

Detail Summary Sheet

Date 1 Sep 81 Prot No.: 81-28 Status: Ongoing

Title: Computer-Aided Diagnosis of Acute Abdominal Conditions.

Start Date: May 81	Est Comp Date:
Principal Investigator: Fred H. Edwards, M.D., CPT, MC	Facility: DDEAMC
Dept/Svc: Surgery	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To establish a computer program that will assist physicians in the diagnosis of acute abdominal pain.

Technical Approach: A Bayesian statistical algorithm has been devised and programmed. The next step will be to generate the clinical data base. Initially, this will be derived from the Leeds system. The program can best be de-bugged using this established data file. After de-bugging, a review of the acute abdominal cases on file over the past two years at DDEAMC will be conducted. This will be translated into a digital matrix for incorporation into the program. A retrospective study will then be performed to assess the diagnostic accuracy of the program. Clinical parameters will most probably require revision at this point. Following that revision, the program will be used to assess patients at the time of their initial evaluation. The diagnostic accuracy will be scrutinized and compared with that of the physicians involved.

Progress: Over 40 cases are now consolidated into the Abdominal Pain Registry. This is providing the basis for a revised data base used in the diagnostic program. A retrospective analysis of all cases of abdominal pain show the computer to be incorrect in four. The clinician was also incorrect in these four cases. Prospectively, the computer has arrived at a correct preop diagnosis more often than has the clinician. While these initial results are promising, there is still much revision necessary to arrive at the end result specified in the original protocol.

Detail Summary Sheet

Date 9 Oct 81	Prot No.: 78-14	Status: Ongoing

Title: Intraocular Lens Study.

Start Date: Nov 80	Est Comp Date:
Principal Investigator: Thomas W. Grabow, M.D., LTC, MC	Facility: Martin Army Hospital USAMEDDAC, Ft Benning, GA
Dept/Svc: Surgery/Ophthalmology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results Apr 81 Continue

Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical Insertion of the Tennant Anchor Anterior Chamber lens.

Progress: A total of 49 IOL have been implanted. Va 20/40 or better in 47 patients. One IOL was removed, poor patient compliance with postop medication yielded an iritis with cyclic membrane formation. Anterior victrectomy necessitated the removal of the IOL, Va 20/300. One patient with Va 20/70 - diagnosed as senile macular degeneration prior to surgery.

Detail Summary Sheet

Date 28 Sep 81 Prot No.: 79-25 Status: Ongoing

Title: The Effect of Guaifenesin in the Treatment of Middle Ear Effusion: A Double Blind Study.

Start Date: Nov 80	Est Comp Date:
Principal Investigator: Gregory H. Blake, M.D., CPT, MC	Facility: Martin Army Hospital USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether guaifenesin, a mucolytic agent has a place in the management of middle ear effusion.

Technical Approach: The study is a double blind protocol looking at children aged 2-16 years who have middle ear effusion. Middle ear effusion is diagnosed by clinical history, otoscopic exam, and audiology evaluation. Audiologic criteria are a Type B tympanogram or two of the following: a difference between air and bone conduction hearing threshold level of .15 dB or more on three test frequencies; a maximum compliance change peak which is negatively displaced 100 mm or more from ambient air; and a static middle ear compliance less than 0.26 ml. Half of those patients agreeing to enter the study will be given guaifenesin and the other half the base of guaifenesin. Patients will be followed for clinical and audiologic improvement at two and four weeks.

Progress: Study progressing well but do not have required patient number to complete protocol objectives.

Detail Summary Sheet

Date: 28 Oct 81	Prot No.: 80-31	Status: Ongoing
Title: Medical Screen and Functional Testing in a Pilot Cohort of Over Age Forty Active Duty Army Personnel to be Trained and Tested in the New Army "Over Forty Physical Training Program."		
Start Date: Oct 80		Est Comp Date:
Principal Investigator: Ronald Albright, M.D., CPT, MC		Facility: Martin Army Hospital USA MEDDAC, Ft Benning, GA
Dept/Svc: Medicine		Associate Investigators: Milton D. Alexander, M.D., MAJ, MC DDEAMC
Key Words:		Kent M. Plowman, M.D., MAJ, MC, DDEAMC
Accumulative MEDCASE Cost: -	Est Accumulative OMA Cost: -	Periodic Review Results

Study Objective: The purpose of this protocol is to attempt to identify latent coronary artery disease (CAD) in asymptomatic active duty military personnel prior to conditioning training. Multiple serial screening procedures will be used to ascertain the safety of aerobic testing/training in individuals over forty years of age, regardless of their initial state of conditioning.

Technical Approach: The strategy proposed is to validate existing screening tests that have been applied to other groups of military personnel. A pilot group will be tested relatively intensively with the intent of identifying the combination of screening procedures having the sensitivity, specificity and predictive vaule necessary to identify a subgroup of individuals at increased rist of cardiac disorders requiring definitive evaluation. A serial screening strategy will be tested as to its sensitivity, specificity, and predictive value. Projections can then be made for the materiel and personnel costs required for an Army-wide screening program prior to cardiovascular fitness testing of all active duty members over age forty.

Progress: The initial screening, training period, and post training screening phases have been completed. Ongoing investigation with thallium stress tests and indicated cardiac catheterizations are still ongoing. Publication of data to date is pending.

Detail Summary Sheet

Date 6 Oct 81	Prot No.: 80-35	Status: Ongoing

Title: A Multi-Clinic, Double-Blind Evaluation of Butibel Tablets vs Sodium Butabarbital vs Belladonna Extract vs Placebo in the Treatment of Irritable Bowel Syndrome.

Start Date: Apr 81		Est Comp Date:
Principal Investigator: Melvin Butler, M.D., COL, MC		Facility: Martin Army Hospital USAMEDDAC, Ft Benning, GA
Dept/Svc: Medicine		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the efficacy, if any, of Butibel in the treatment of Irritable Bowel Syndrome.

Technical Approach: This study is being done in a double-blind fashion.

Progress: To date 14 patients have been enrolled in the project, of whom 12 have completed the 4-week course of therapy. Since the study is done in a double-blind fashion and the code will not be broken for some time yet, no conclusions can be drawn. The 3 patients who failed to complete the study each complained of side effects. The symptoms included drowsiness, dry-mouth and dizziness.

Detail Summary Sheet

Date: 21 Oct 81 | Prot No.: 81-25 | Status: Ongoing

Title: Multicenter Outpatient Trial of Topical DMSO Gel (35% & 70%) in the Short-Term Treatment of Acute Musculoskeletal Strains and Sprains and Other Acute Traumatic Musculoskeletal Conditions.

Start Date: Jun 81	Est Comp Date:
Principal Investigator: Leroy R. Fullerton, M.D., LTC, MC	Facility: Martin Army Hospital USA MEDDAC, Ft Benning, GA
Dept/Svc:	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the effectiveness of DMSO in strengths of 35% and 70%.

Technical Approach: Apply DMSO gel and follow signs and symptoms.

Progress: Four of 40 patients tested. Blind study, results unknown.

Detail Summary Sheet

Date 9 Oct 81 | Prot No.: 81-13 | Status: Ongoing

Title: Evaluation of Live, Attenuated, Intranasally Administered Vaccines in Open Trials in Young Children.

Start Date: Dec 81	Est Comp Date: Spring 1982
Principal Investigator: Robert A. Walker, M.D., LTC, MC	Facility: USAMEDDAC, Ft Campbell, KY
Dept/Svc: Pediatrics	Associate Investigators: Peter F. Wright, M.D. Vanderbilt Univ Medical Center
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Attempt to determine if the two cold-adapted vaccine strains which share the same attenuated genes from the master A/Ann Arbor/6/60 strain have the same level of infectivity and clinical. Will any minor reproducible pattern of clinical illness emerge when vaccines are given on a larger scale? Can the vaccines be shown protective against homologous or related naturally circulating strains?

Technical Approach: Nasal administration of either A/USSR or A/ALASKA live attenuated viral vaccines to well children 1-3 years of age. Follow up visits on day 3,6, 1 month and after flu season. Blood is drawn on day of vaccine, one month later and after flu season. Throat cultures are done days 0, 3 and 6.

Progress: Due to the time constraints before the flu season started last year, only 20 children received vaccine. Of the 9 children who received A/ALASKA, all 9 had antibody rises to the virus. Of the 11 who received A/USSR, only 5 of 11 had a titer rise. The A/ALASKA vaccine is more antigenic, as expected. Also, clinically, none of the 9 who received A/ALASKA had the flu, while among age-matched controls 14 of 29 (50%) had documented antibody rises to A/Bangkok (current flu epidemic). Since the current flu virus remains the same as last year, the nasal flu vaccines will be given again to a larger number of children.

Detail Summary Sheet

Date 9 Oct 81	Prot No.: 81-26	Status: Ongoing

Title: Three-Way Double-Blind Efficacy Trial of Topical 35% DMSO Gel and 70% DMSO Gel vs 1% DMSO Gel as Control in the Treatment of Acute Ankle Sprains.

Start Date: Jul 81		Est Comp Date:
Principal Investigator: Stephen J. Frushour, M.D., LTC, MC		Facility: USAMEDDAC, Ft Campbell, KY
Dept/Svc: Surgery/Orthopedics		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Evaluate the effectiveness of DMSO in the treatment of moderate to severe ankle sprain.

Technical Approach: Topical application of drug TID. Clinical evaluation before, during and after application for one week. Drug and urine studies before and after application.

Progress: Twenty-six volunteer patients have been treated in this triple blind study to date. There have been no problems or severe side effects. The goal is to treat 90 patients in this study.

Detail Summary Sheet

Date 9 Oct 81	Prot No.: 78-14	Status: Ongoing

Title: Intraocular Lens Study.

Start Date: Jul 81		Est Comp Date:
Principal Investigator: Norman T. Byers, M.D., LTC, MC		Facility: Moncrief Army Hospital USAMEDDAC, Ft Jackson, SC
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results Apr 81 Continue

Study Objective: Insertion in selected patients of Tennant Anterior Chamber Anchor Lens.

Technical Approach: Using routine intracapsular cataract techniques, the lens would be inserted prior to final closure of the wound.

Progress: As of this date, four surgeries have been used with the intraocular lens. The first case on 10 Jun 81 was aborted due to vitreous prolapse. The patient had a successful outcome. The second was performed on 9 Jul 81 with excellent results with the patient having a resultant visual outcome of 20/25 in the eye with the intraocular lens. The third lens was implanted on 29 Jul 81 with the patient seeing 20/20 in the eye with the intraocular lens. The fourth intraocular lens case was done on 31 Aug 81 at which time the case was aborted due to inability to maintain the anterior chamber during the procedure. All four have had good outcomes even though only two have had successful implantations. Approximately seven additional cases with intraocular lenses are scheduled over the next three motnhs.

Detail Summary Sheet

Date 2 Oct 81 | Prot No.: 78-14 | Status: Ongoing

Title: Intraocular Lens Study.

Start Date: Oct 80		Est Comp Date:
Principal Investigator: Nicholas E. Barreca, M.D., COL, MC		Facility: Lyster US Army Hospital USAMEDDAC, Ft Rucker, AL
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words: Intraocular Lens, Implant, Ophthalmology, Aphakia, Surgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Apr 81 Results Continue

Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.

Technical Approach: Currently accepted surgical techniques for cataract extraction and intraocular lens implantation using the operating microscope.

Progress: Since the start of this study at LUSACH in October 1980, there have been 15 anterior chamber intraocular lenses implanted. Of the first nine patients implanted, final visual acuities have been no worse than 20/25 in the operated eye. The majority of patients have achieved 20/20 visual acuity. The last six patients have been operated on more recently and final corrected visual acuities are not available. There have been no serious complications as the result of any of our surgical implantations. No adverse reports have been submitted. At the present time, A Scan ultra sonography is obtained to determine axial length in all patients preoperatively.

Detail Summary Sheet

Date 5 Oct 81	Prot No.: 81-39	Status: Ongoing

Title: Long-term Suppression of Atrophie Blanche with Use of Phenformin.

Start Date: Sep 81	Est Comp Date:
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Dept/Svc: Medicine	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To continue to suppress Atrophie Blanche in a patient placed and controlled on Phenformin and Ethylestrenol therapy since September 1972.

Technical Approach: Only one patient will comprise the investigation. The patient is selected because of well documented medical history of the disease Atrophie Blanche to include publication of the circumstances and treatment of this specific case in Archives of Dermatology, Vol 109, May 1974, pages 664-666 (Case 5). Additionally, the treatment regimen to be employed has been successfully ongoing since 1972.

Progress: This study received TSG approval on 28 Sep 81, no reportable data available.

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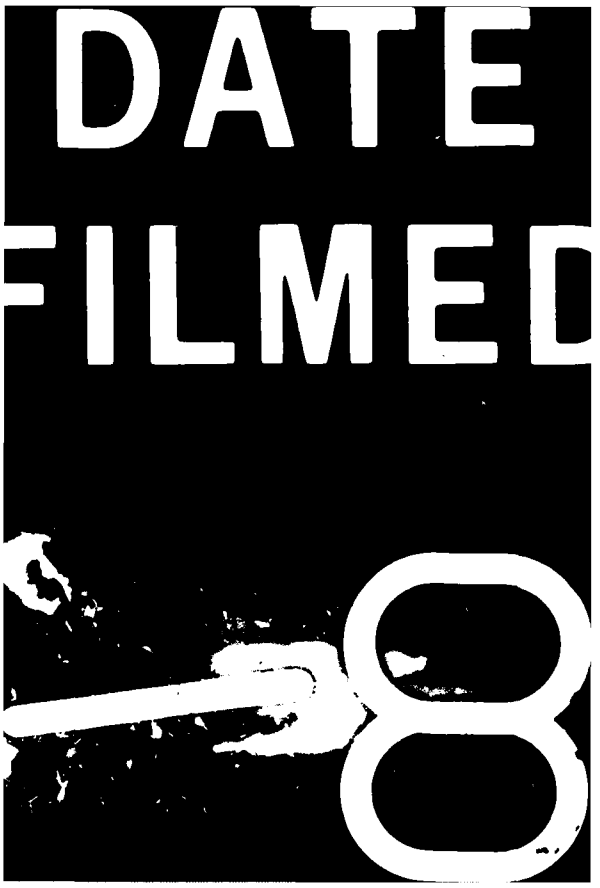
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